Washington State Patrol
Crime Laboratory Division

Quality Operations Manual

April 2018

1 INTRODUCTION

The purpose of the Crime Laboratory Division (CLD) Quality Operations Manual is to provide CLD staff with written policies and procedures that:

- Promote an efficient and effective operation within the CLD;
- Assist CLD staff in performing assigned duties and tasks;
- Ensure that the work product of the laboratory is of the highest quality possible;
- Help to demonstrate that the CLD operates a quality management system, is technically competent, and is able to generate technically valid results.

This manual also describes the Quality Assurance Program of the CLD and provides personnel with a description of the Division's policies for maintaining an effective quality assurance program. This program applies to all work done in all areas within the CLD and the policies and procedures are binding on all personnel of the CLD and shall be adhered to.

The official version of this manual is the electronic version on the Forensic Laboratory Services Bureau (FLSB) Portal, the Bureau's SharePoint site.

2 SCOPE

2.1 MISSION STATEMENT

The Washington State Patrol (WSP) CLD will provide forensic science services and training for Washington's criminal justice agencies. The CLD is committed to providing the highest quality forensic services which ultimately enhances public safety for the citizens of Washington. The WSP CLD adheres to the WSP Mission Statement.

The Washington State Patrol makes a difference every day, enhancing the safety and security of our state by providing the best in public safety services.

2.2 VISION

Our vision is to be recognized as an international leader in forensic science services.

2.3 VALUES

Every employee is a critical member of a team committed to professional excellence through:

- Customer service
- Unbiased and fair expertise
- Protecting individual rights
- Strong leadership
- Effective partnerships
- Integrity and accountability
- Public trust and confidence
- Technical advancement

2.4 GOALS AND OBJECTIVES

The goals and objectives of the CLD will be reviewed continually and are based upon the needs of the Criminal Justice System and the needs of the customers served by the respective laboratories.

2.5 LEGAL MANDATE

The Washington State Patrol Crime Laboratory Division is a publicly funded, legal entity and is responsible for its legislatively mandated actions. The CLD provides scientific and technical examinations for all criminal justice agencies as mandated by RCW 43.43.670. The CLD also provides training assistance to the law enforcement agencies of Washington State.

3 DEFINITIONS

Additional definitions for more specific terms related mostly to a particular chapter are in the respective chapters.

1. Accuracy

The ability of a measurement result to report the true or target value of the property being measured; the degree of conformity or nearness of a measurement to a standard or a true value.

2. Accreditation Cycle

The period of time between full on-site assessments by the accrediting body, generally a period of approximately four (4) years.

3. Administrative Documentation

Documentation either received or generated by the laboratory that do not constitute data or information resulting from testing. Administrative documentation includes records such as case related conversations, evidence receipts, description of evidence packaging and seals, printouts of thumbnail images, investigative reports and other pertinent information.

4. Administrative Review

Final review for non-technical matters of the case file and final report prior to release of the report to the customer.

5. Amended Report

A report generated to correct errors, make additions to, or improve wording in a previous laboratory report.

6. Annual

Annual in this manual refers to the calendar year unless otherwise specified.

7. Calibration

The process used to establish that equipment is capable of achieving the discipline's and the manufacturer's specifications for the test and by which known traceable standards having unbiased reference values are introduced into an item of equipment. The equipment is then adjusted (either by software, hardware, electronics, etc.) to report the known reference value.

8. Casework

Analytical work performed by a forensic scientist or technician. Generally this involves the examination and analysis of physical evidence, but is extended to include the processing and analysis of convicted offender DNA samples by scientists in the CODIS laboratory, and the entry and correlation of ammunition components in the National Integrated Ballistic Information Network (NIBIN).

9. Case File

Administrative and examination documentation pertaining to a case that is received or generated by the laboratory.

10. Case Record

A case record, or test record, is all administrative and examination documentation pertaining to a case that is received or generated by the laboratory. Information in the case record may be in the case file or in other locations in the laboratory which are designated as extensions of the case file.

This may include, but is not limited to:

- Administrative and examination documentation maintained in the case file
- Electronically stored data
- Chain of custody documentation (including LIMS)
- Digital images
- Instrument maintenance and verification documentation
- Reagent and standard quality control documentation
- Submitting agency/customer information, including name and address

Information in the case record may be in the case file or in other locations in the laboratory which are designated as extensions of the case file.

11. Certified Reference Material (CRM)

A material or substance, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes traceability to an accurate realization of the unit in which the property values are expressed. Each certified value is accompanied by an uncertainty at a stated level of confidence. An example of such a CRM would be a NIST traceable ruler.

12. Competency Test

The final examination provided to a trainee at the end of training modules or at the end of the training plan for a specific functional area discipline.

13. Consensus Standards

Consensus standards are voluntary standards that are accepted and agreed upon within an industry by bodies such as ASTM.

14. Correction

Immediate action taken to eliminate a detected nonconformity (a correction can be made in conjunction with a corrective action).

15. Corrective Action

The overall actions taken and plan or process used to address a nonconformity and to eliminate the cause of a detected nonconformity or other undesirable situation.

16. Corrective Action Plan (CAP)

A formal statement by the supervisor or designated authority prepared and entered using the RNTP, detailing the following:

- Description of the incident (what is the nature of the nonconformity?)
- Root cause analysis (including the chain of events leading to or causing the nonconformity)
- The immediate corrective actions taken (how was the problem handled?)
- Preventive action to avoid future occurrences
- A timeline for completion of the corrective and preventive actions
- A recommended schedule for follow-up to determine the effectiveness of the preventive measures to be taken (if required)

17. Corrective Action Report

A summary report in IOC format, prepared by the supervisor or designated authority upon the conclusion of a corrective action (if required).

18. Court Testimony Review

To oversee, evaluate or monitor testimony provided in a court of law under oath.

19. Division Operational Plan

The CLD Operational Plan is a document comprised of goals and objectives outlining the intended direction of the Crime Laboratory Division. This plan has the stated strategies (action items) detailing how the goals and objectives will be achieved.

20. Division Objectives

Objectives are general statements that address critical issues by breaking down goals into smaller, more specific pieces. Generally, there should be an objective assigned to each critical issue within the Division. Objectives drive actions and represent the general end toward which the Division efforts are directed. An objective should provide a sense of the level of performance expected.

21. Division Strategies

Strategies state how the Division is going to accomplish the stated Division objectives. They include an action plan along with performance measures in order to determine to what level the objectives are achieved.

22. Draft Report

A preliminary version of a report prior to its issue under laboratory letterhead. A final draft should be as free from errors as possible. Minor administrative errors may be

noted and corrected on the final draft but the final report must reflect these corrections. (Note: The CODIS Laboratory does not issue reports.)

23. Equipment

Instruments or devices used to measure, record or identify any entity, and having a significant effect on the accuracy or validity of the result of the test, calibration or sampling, as determined by requirements in the functional area technical procedures: Also called test equipment.

24. Examination Documentation

Usually generated by the laboratory and includes reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, case notes, documentation of observations and results of examinations or tests, photographs, etc.

25. External Assessment

A review conducted by personnel from outside the CLD which compares the various aspects of the laboratory's performance against stated requirements, standards, policies and procedures.

26. Fully Documented

Documentation as to the source of the material and the date it was acquired (if known). Documentation may be made on the reference material itself, on its proximal packaging, or as part of a database record.

27. Internal Audit

A review conducted by CLD personnel to compare the various aspects of the laboratory's performance against stated requirements, standards, policies and procedures.

28. Internal Validation

Validation that occurs within the CLD by qualified CLD personnel.

29. Laboratory Developed Methods

Methods developed in house as standard methods for a specific laboratory purpose.

30. Laboratory Report

The formal results of the requested analysis, issued under laboratory letterhead that is returned to the requestor.

31. Management System Review (MSR)

A Management System Review is an annual review by management of the laboratory management and quality systems, and its testing activities to ensure continuing suitability and effectiveness. The finding of this review will be used as a tool to introduce necessary changes or improvements by management.

32. Method

Any technical procedure detailing the use of reagents and/or instrumentation for scientific analyses, synonymous with “test procedure”.

33. Modified Method

Standard scientifically validated and forensically adopted method that is used outside the intended scope, or has been amplified or modified.

34. Non-Standard Method

A scientifically validated method or procedure that is not typically applied or used for forensic analysis.

35. Objective Evidence

Data supporting the existence or verity of something: may be obtained through observation, measurement, test or other means.

36. National/International Standard

A standard recognized by national or international agreement to serve as the basis for assigning values to other standards of the quantity concerned. The standards which generally apply are the metric system of measures expressed in SI units, the units of the International System of Units.

37. National Institute for Standards and Technology

This federal agency, also known as NIST, is located within the Department of Commerce and represents the final authority for metrology in the United States. Ideally, all measurement results should be documented and shown to be traceable to NIST.

38. Nonconformity of Test/Work (nonconformance)

Non-fulfillment of a test/work requirement; failure to appropriately follow or apply accepted protocols in case work; any aspect of testing that does not agree with established laboratory, technical or quality system procedures or requirements.

Inefficiency in work or behavioral issues in work performance are not necessarily a nonconformity.

39. Opinions and Interpretations

A formal expression of judgment based upon the analyst’s interpretations of observations or data.

40. Performance Verification

A set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer’s specifications or CLD specified parameters, or to determine if a validated method is fit for purpose and performing as expected.

41. Precision

The degree of agreement or repeatability among replicate measurements performed at the same time, on the same instrument, by the same operator and under the same conditions. Precision is quantified by the standard deviation.

42. Properly Controlled

Access to reference materials under the control of the laboratory is restricted to those persons authorized by the laboratory manager.

43. Quality

Adherence to generally recognized standards of good laboratory practice.

44. Quality Assurance (QA)

Those processes and systematic actions necessary to provide confidence that the laboratory's work product and services will satisfy given requirements for quality.

45. Quality Assurance Audit

A systematic examination and review to determine whether quality processes and related results comply with the CLD protocols, policies, and procedures, and whether these practices are suitable and effective in achieving the quality objectives.

46. Quality Operations Manual

A collection of the CLD quality system policies and objectives and how these policies and objectives will be implemented.

47. Quality Assurance Program (QAP)

A planned system of activities describing requirements for forensic analyses and reporting, the purpose of which is to provide confidence that the work product and services provided by the CLD are scientifically sound and valid.

48. Quality Control (QC)

Internal activities or activities conducted according to externally established standards used by the CLD laboratories to consistently ensure accurate analytical results.

49. Quality Management System

The total organizational structure, responsibilities, policies, procedures, and resources for implementing quality management. This includes all activities which directly or indirectly contribute to quality.

50. Quality Assurance Records

Records, logs, worksheets and electronic files that provide documented support of conformity to the quality management system. These records include, but are not limited to, method and equipment validation documents, equipment verification records, reagent and chemical QC logs, training records, proficiency and competency test records, courtroom testimony monitoring records and audit records.

51. Reference Material

A collection of data or item/materials which may be encountered in casework which are maintained for identification, comparison or interpretation purposes.

52. Reference Standard

A sample acquired or prepared that has known properties (e.g., concentration, chemical composition) for the purpose of calibrating equipment, verifying performance and/or for use as a control in experiments.

53. Remedy Nonconformance Tracking Program (RNTP)

The electronic data system used to track nonconforming work and corrective actions.

54. Request

The analysis asked to be performed by the submitting agency on evidence received in the laboratory. An agency may request analysis in any one of the disciplines available through the CLD. The request is formally made by completing and submitting the Request for Laboratory Examination, Form 3000-210-005 (RFLE).

55. Substantive Nonconformance

A substantive nonconformance is an incident where the nature or cause of the nonconformity directly affects, raises immediate concern and has a fundamental, substantive impact on the work product of the laboratory or the integrity of evidence; or there is concern that if the nonconformance continues for an extended period the work product of the laboratory or integrity of evidence could be negatively affected. An example is a technical error in a submitted case report that requires the issuance of an amended report.

56. Supervised Casework

Casework conducted by an analyst that is monitored by the trainer or other proficient and experienced scientist to ensure casework approach, documentation, procedures and methods are appropriately applied.

57. Supervisor Review

General review of case records by a supervisor to maintain oversight of laboratory operations.

58. Technical Procedures

Scientific methodologies used in forensic analyses. Written procedures will be prepared for routine tests performed in the CLD Laboratories. The procedures used may be those developed and validated in–house or by an outside laboratory.

59. Technical Record

Examination documentation, laboratory reports, amended reports and draft reports.

60. Technical Review

Review of examination documentation, draft reports and testimony to ensure the validity of test results, opinions and interpretations and that proper procedures were used and documented.

61. Testimony

A statement made under oath as a witness.

62. Traceability

The property of a measurement result whereby it can be related to standard references, usually national or international, through an unbroken chain of comparisons all having stated uncertainties.

63. Trainee

A trainee is any employee of the CLD who is training in a new discipline, functional area or job classification. Trainees can be permanent, non-permanent, probationary or trial service. Please refer to the Collective Bargaining Agreement and HRD for clarification of employee status.

64. Training Procedures

The foundational training program required for all qualified forensic scientists in their discipline prior to assuming forensic analysis.

65. Uniquely Identified

An item is uniquely identified when each item or group of similar items has a unique name or identifier. This may be a laboratory generated number, database generated number or simply the name of the item if it is unique.

66. Validation

Confirmation, through the provision of objective evidence, that the particular requirements for a specific intended use or application have been fulfilled and is fit for purpose.

67. Verbal/Email Reports

Oral or emailed communication of technically reviewed analytical results given prior to completion of a formal written case report.

68. Verification

The procedure used to evaluate the validity of a test result/opinion reached by re-performing the comparison between the unknown and the known.

69. Yearly

Within the calendar year, and no sooner than four months from the previous action.

4 QUALITY ASSURANCE PROGRAM

4.1 QUALITY MANAGEMENT SYSTEM AND ASSURANCE PROGRAM

4.1.1 POLICY

The CLD will establish, implement and maintain a quality management system appropriate to the scope of its activities. The CLD will document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test results. The system's documentation will be communicated to, understood by, available to, and implemented by the appropriate personnel. The CLD Quality Management System policies, procedures and objectives are defined in this Manual.

The laboratory management is committed to complying with ISO and any supplemental standards and the policies and procedures described herein and will proactively strive to continually improve the effectiveness of the Quality Management System.

The documentation upon which the Quality Management System is built includes this manual, all technical procedures and training manuals, safety manuals, DNA Quality Assurance and FBI Quality Assurance Standards manuals, and the Forensic Services Guide. The Quality Operations Manual has over-riding authority over all technical procedures manuals, including LIMS Policies and Procedures. The Washington State Patrol Regulation Manual has over-riding authority over all FLSB Manuals.

Laboratory managers and supervisors are responsible for ensuring that the policies and procedures adopted by the CLD are implemented and integrated into the daily operations of the laboratory. Laboratory managers are also responsible for overseeing and monitoring and ensuring compliance to the Quality Management System. In this respect, they function as quality assurance managers for their individual laboratories.

4.2 QUALITY POLICY STATEMENT

The CLD, its management, and its employees, are committed to professional excellence. All CLD employees will work to continually maintain the highest degree of quality and integrity of laboratory services and to ensure that forensic conclusions are scientifically sound and valid.

To this end, all laboratory analyses and related services performed by the laboratory system shall meet generally recognized standards of the forensic community and its accrediting organizations. Specifically, the CLD shall carry out all testing activities in accordance with stated methods, the requirements of the customer, the State of Washington and federal regulatory authorities and the ISO 17025:2005 standards (hereafter ISO) and any supplemental standards required by the accrediting organization. National DNA Index System (NDIS) participating laboratories shall conform

to requirements in the NDIS Operational Procedures Manual and in applicable FBI Quality Assurance Standards.

The CLD embraces and supports the principles presented in the ANAB *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*, which includes statements addressing Professionalism, Competency and Proficiency, and Clear Communications.

The CLD Quality Management System is designed to continually improve the quality and level of services provided to Washington's Criminal Justice System and to assure the credibility of the CLD. This will be accomplished by providing quality service and audits through every area of the division. The CLD Quality Operations Manual is binding on all personnel of the Division and shall be adhered to.

All employees are required to familiarize themselves with the appropriate manuals and implement the CLD quality assurance policies and procedures in their work. In doing so, the CLD will maintain the highest level of staff expertise and analytical abilities, promote staff confidence, and conform to the ISO accreditation standards and any supplemental standards. DNA forensic scientists have additional quality requirements which can be found in the DNA Quality Manual and the FBI DNA Quality Assurance Standards document.

Laboratory management is committed to complying with ISO and any supplemental standards and the policies and procedures described herein and will proactively strive to continually improve the effectiveness of the Quality Management System.

The commitment to implement a successful Quality Management System begins with the CLD Commander and is supported by a commitment from the Standards and Accountability Section. As the CLD Commander and the Quality Assurance Manager, we therefore affirm our commitment to this quality policy statement, a signed copy of which is available on the FLSB Portal.

4.3 QUALITY ASSURANCE OBJECTIVES

The objectives of the CLD overall quality assurance program are:

4.3.1 Service

To provide quality service to Washington's Criminal Justice System by using procedures that are valid, reliable and sufficient for the intended purpose, and by meeting customer, statutory and regulatory requirements.

4.3.2 Standardization

To bring uniformity to the technical policies and procedures across the Division with the intent of producing high quality work that satisfies the customer's requirements for service and meets the accrediting body's standards.

4.3.3 Training and Education

- To provide training to CLD personnel in their area of expertise,
- To provide training to CLD personnel in the quality management system,
- To provide growth opportunities for CLD personnel,
- To facilitate involvement of CLD personnel at the national and international level,
- To provide continuing education to our customers regarding CLD services, policies and procedures.

4.3.4 Accreditation

To maintain laboratory quality, excellence and reliability by conforming to accreditation standards and maintaining accreditation requirements.

4.3.5 Review

To proactively review and monitor the Quality Management System to identify potential nonconformities to standards.

4.3.6 Audit

To assess and document quality assurance activities through an audit process in order to demonstrate conformance to accreditation standards and maintain trust in the work product.

4.3.7 Survey and Communication

- To facilitate and enhance communication within the organization.
- To conduct surveys and maintain open communication with customers.
- To review and analyze customer requirements and satisfaction with the CLD services.
- To communicate to all CLD personnel the importance of meeting customer requirements as well as statutory and regulatory requirements.

In order to adhere to the Quality Assurance Program and meet quality assurance objectives, the CLD will:

- Use established technical procedures in laboratory analyses that are reliable, reproducible, accepted in the forensic science community and adequate for the intended purpose.
- Participate in a proficiency testing program to monitor the routine operational performance of the laboratory.
- Provide sufficient training to all staff. Continuing education and professional career development training will be available to all staff as necessary to provide the best possible work product.
- Conduct regular court testimony monitoring of staff members.

- Have an employee performance evaluation program in which the tasks, responsibilities, safety and career development needs of the employee are reviewed each year.
- Have a system of technical and administrative review for case files and reports.
- Undergo an annual quality assurance audit. This audit will be the responsibility of the Standards and Accountability Section (SAS). The quality assurance audits ensure that the CLD stated policies and procedures are being followed.
- Have an annual management system review to include a review of the quality assurance program, and discuss this review at scheduled management meetings. Information from these meetings will be communicated to all CLD staff by the SAS. This review will generally be conducted in the first quarter of the year.

5 STRUCTURE, SERVICES AND FUNCTIONS

5.1 ORGANIZATION

The CLD is a part of the WSP FLSB. The CLD Headquarters, Combined DNA Index System (CODIS) Lab and Seattle Crime Lab are co-located in Seattle. The Standards and Accountability Section (SAS) is also co-located in Seattle and reports to the FLSB Director. FSLB Headquarters is located in Olympia. The Division has laboratories located in Kennewick, Marysville, Olympia, Seattle, Spokane, Tacoma, and Vancouver.

The CLD will provide services in scientific examination of physical evidence, collection and preservation of evidence, and expert testimony regarding the scientific examinations according to the legal mandate listed above. Training will be provided to law enforcement agencies within the state in the collection and preservation of evidence, and crime laboratory capabilities.

5.2 SERVICES

The CLD laboratories provide examination and casework services in the following forensic disciplines (also referred to as functional areas):

5.2.1 Materials Analysis

Scientists in this functional area identify controlled substances, pharmaceuticals, materials from clandestine drug laboratories, ignitable liquids and ignitable liquid residues in fire debris, explosives and post-blast explosive residues, selected poisons, chemical unknowns, examine and compare trace materials such as hairs, fibers, glass, paint, impression evidence, soils and other miscellaneous materials. Scientists who have the appropriate training may be consulted for assistance with clandestine lab and investigations.

5.2.2 Firearms and Toolmarks

Scientists in this functional area examine and compare firearms, ammunition components, gunshot residues for distance determinations, and toolmarks. These scientists also reconstruct shooting scenes, restore obliterated serial numbers, and image fired ammunition components for inclusion in the Integrated Ballistics Identification System (IBIS)/ National Integrated Ballistics Information Network (NIBIN).

5.2.3 DNA

Scientists in this functional area characterize biological stains and extract and type human DNA from biological evidence. The DNA typing profiles obtained can be compared to the DNA of known individuals and/or entered into the CODIS database.

5.2.4 Combined DNA Index System (CODIS)

Scientists in the CODIS Laboratory type convicted offender samples for the CODIS database and manage the statewide CODIS database.

5.2.5 Questioned Documents

Scientists in this functional area examine and compare handwriting, hand printing, altered documents, indented writing, machine-generated documents, paper and ink.

5.2.6 Latent Prints

Scientists in this functional area process evidence for latent prints and compare the prints to those from known individuals. These scientists also enter prints into and search a variety of databases.

5.2.7 Crime Scene Response

Participating scientists are members of the Crime Scene Response Team (CSRT) and provide crime scene assistance to law enforcement agencies investigating major crimes. These scientists assist the agency with evidence recognition, evidence collection, bloodstain pattern analysis and trajectory determination, scene documentation, and scene reconstruction.

CSRT full-time and part-time responders share the responsibility to produce timely reports and technical reviews and to testify in court. Part-time responders must also balance these needs with their regular case work and other assignments.

Part-time crime scene responders are expected to:

- Be on call for a week at a time on a predetermined rotation schedule.
- Dedicate their time during their on-call week, to
    - callouts
    - report writing
    - technical review
    - training and continuing education
    - vehicle/supply/equipment maintenance and ordering
    - any other crime scene related responsibilities or issues
- Revert to the duties in their regular discipline if the CSRT member has no pending CSRT related duties.

Supervisors must allow part-time CSRT members to focus on CSRT duties during their on-call week. Exceptions may be necessary for court appearances or to complete rush cases from the CSRT member's regular discipline. When these exceptions occur, the supervisor will notify the CSRT Manager or designee. In the reverse circumstance, an extraordinary CSRT callout or rush CSRT report or review may take the CSRT member away from regular discipline duties during non-callout times. This will be coordinated between the member's regular supervisor and the

CSRT Manager or designee. The CSRT Manager or designee and the supervisor of the part-time CSRT responder should work to resolve any issues that arise due to conflicting priorities.

While responding to a crime scene, all responders, full-time and part-time, are working under the supervision of the Crime Scene Response Team Manager or designee. Technical questions that arise at the scene will be referred to the CSRT Manager or designee.

5.3 BUDGET

The CLD budget is part of the FLSB overall budget. Overall responsibility of this budget is under the direction of the FLSB Director. The CLD Commander is expected to manage, direct, and develop the CLD budget with oversight from the Bureau Director. The CLD Commander will keep the local Laboratory Managers informed of the status of the budget through the monthly Strategic Advancement Forum (SAF) report. The local Laboratory Managers have no individual laboratory budgets but are expected to manage operational expenditures at their level.

5.4 COMMUNICATIONS

5.4.1 Policy

The CLD Commander, Laboratory Managers and Supervisors will establish a proper flow of communication internally throughout the CLD and externally with our customers. Management will ensure that within each laboratory all employees are well informed and employees at each level have input into the system. In addition, management will ensure that communication with our customers is effective and responsive to our customers' needs.

Examples of various forms of communication to be used internally by the CLD include but are not limited to the following:

- Managers meetings
- Supervisors meetings
- Local Manager/Supervisors meetings
- Laboratory meetings
- Section meetings
- Conference calls
- Functional area meetings
- Interoffice Communications (IOC)
- E-mail
- FLSB Portal

Some examples of external communication are as follows:

- Personal contact by telephone, e-mail, letter, or in person

- Attendance at meetings of local law enforcement, prosecutors or medical examiners
- Forensic Investigation Council meetings
- Customer newsletters
- FLSB Forensic Services Guide
- Training provided to law enforcement, prosecutors or SANE nurses
- Membership and participation in WSP or State committees
- Customer surveys

The extent of database (e.g., CODIS, AFIS, NIBIN) searches shall be communicated to customers in the Forensic Services Guide and updated as needed, or in the laboratory report where applicable, and updated as needed.

5.4.2 Chain of Command

The chain of command is the hierarchical structure of authority and responsibility along which information is passed. The chain of command works in both directions. (See Organization Charts on FLSB Portal).

CLD employees will follow the chain of command for all internal communications as required by WSP Regulation 10.01.010. The chain of command, in ascending order, will normally be the employee's Supervisor, the Laboratory Manager, the CLD Commander/Designee, the FLSB Director and the Chief of the Washington State Patrol.

The reporting authority is as follows:

- The Laboratory Managers report to the CLD Commander. Lab Supervisors report to the Laboratory Managers.
- Each staff member is accountable to one and only one Laboratory Supervisor for each forensic discipline.
- The Quality Assurance, Quality Process, and Laboratory Accreditation Managers may direct work to laboratory personnel and Technical Leaders within the Quality Program.
- Approval for use of personnel for Quality Assurance program projects is by the employee's supervisor or manager.
- When a supervisor or manager is unavailable, a person will be designated as the acting supervisor or manager.

If no one is available to take this responsibility, the next most responsible level of the chain of command will be in charge.

5.5 CUSTOMER FEEDBACK

Customer feedback, both positive and negative, will be solicited. This may be accomplished through any of a number of methods:

- a periodic statewide customer survey
- a local focus group conducted by an individual laboratory manager and staff
- questionnaires submitted randomly to limited numbers of customers
- other direct interaction, both formal and informal, with specific customers.

The objective is to gather information to provide insight into the wants and needs of the customer agencies and how we can improve our service.

The decision to submit a statewide customer survey will be made jointly by the Laboratory Managers and the CLD Commander. Individual Lab Managers are responsible to document use of any other methods to collect feedback along with the feedback itself from their own service area. Customer feedback will be reviewed and addressed at the annual management review.

Laboratory staff shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory appropriately ensures confidentiality to other customers (ISO 4.7.1).

5.6 COMPLAINTS

5.6.1 Policy

A complaint is an allegation of conduct or omission that is contrary to state statute, Washington Administrative or Civil Service Rules, Bargaining Unit Agreement, WSP Agency or CLD policies, regulations, rules, and procedures. They may include Quality Assurance policies and procedures, or an allegation of conduct or omission that could amount to misconduct, exercise of poor judgment, or failure to meet established standards. A complaint may be made against an individual CLD employee, a laboratory, a procedure or the Division.

Complaints regarding laboratory personnel, policies or procedures may come from internal or external sources (e.g., officers, prosecutors, defense attorneys, and the public). Complaints could be written or communicated orally. Personnel that become aware of a complaint either from an internal or external source have the responsibility to communicate the complaint through their chain of command. Management has the responsibility to ensure that complaints are resolved appropriately, using one of the procedures outlined below.

5.6.2 Procedure

Non-Quality System complaints follow the WSP Agency Complaint Procedures (WSP Regulation Manual 12.00.020 Complaints).

Complaints regarding any aspect of forensic testing and results of forensic analyses that do not conform to quality policies and/or procedures shall be directed to the

Quality Assurance Manager. Procedures outlined in the section on Nonconforming Work and Corrective Actions shall be followed in these cases.

If management determines that the complaint originated due to a misunderstanding of laboratory policy, the manager may respond directly to the complainant and attempt to resolve the issue by discussing existing policies. Corrective or preventive actions may be initiated as a response as necessary.

Any changes or revisions to controlled documents resulting from complaints will follow the Document Control and Document Revision Policy and Procedure section of the Quality Operations Manual.

5.7 UNDUE INFLUENCE ON ANALYSIS

5.7.1 Policy

The management of the CLD strives to ensure there is no influence on the professional judgments of employees, including any undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work. Personnel shall not engage in activities that may diminish confidence in the laboratory's competence, impartiality, judgment, or operational integrity. A conflict of interest, or an appearance of a conflict of interest, may arise when an employee has a personal relationship outside of work or a financial relationship with a suspect, victim, witness, police officer, attorney or judge involved in a case. This may include a relative or close friend personally or financially involved with any of the groups listed above. This list does not exhaust the possibilities of a conflict of interest. Even in cases where the employee doesn't think that a conflict exists, a possible conflict of interest may exist in the eyes of an observer, which could lead to a diminished confidence in the laboratory and its work.

5.7.2 Procedure

Conflict of interest concerns and situations that could cause undue pressure that adversely affect the quality of the work shall be brought to the attention of management. Laboratory Managers have the responsibility and authority to take action on employee concerns within their lab.

Serious instances of undue influence or conflict of interest will be reported in accordance with the WSP Regulation Manual.

5.8 CONFIDENTIALITY

Every employee has the responsibility to safeguard all confidential information obtained in his or her official capacity from unauthorized distribution. In addition, employees will not access or disclose any confidential information except where authorized (see section on Disclosure and Release of Information). Subcontractors

will sign a statement declaring that they will abide by this confidentiality policy. See also WSP Regulation Manual 8.00.240 CODE OF ETHICS – EMPLOYEES.

5.9 ETHICAL AND PROFESSIONAL RESPONSIBILITIES

Employee training and functional area training manuals shall include the application of ethical practices in forensic sciences. Many resources exist for review of ethical and professional responsibilities. These include, but are not limited to:

- American Academy of Forensic Sciences Code of Ethics and Conduct
- WSP Regulation Manual Chapter 8 Rules of Conduct (annual review required to be completed and documented)
- Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel

5.9.1 Guiding Principles

Laboratory managers will conduct and document ethics training each calendar year with their employees. The *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* shall be reviewed annually by all laboratory personnel. The review will be documented by each laboratory submitting the completed electronic email voting record of their staff to the Quality Process Manager.

5.9.2 Cognitive Bias

Forensic Laboratories establish routine quality assurance and quality control procedures to ensure the accuracy of forensic analyses and the work of forensic practitioners. These quality control procedures should be designed to minimize cognitive bias. There are several different techniques that can be used to manage or recognize cognitive bias. Training manuals in the functional areas may incorporate these tactics in ways that are most appropriate for the category of testing. All new employees will receive training in cognitive bias. Training materials are available on the FLSB Portal and include a “Cognitive Bias” PowerPoint presentation and selected articles. Additional training details can be found in the functional area training manuals.

6 CLD MANAGEMENT AND PERSONNEL

Top management for the CLD begins with the Bureau Director, who is responsible for all Bureau operations and management. Top management also includes the CLD Commander who sets direction for the Division laboratories.

Key management positions consist of the local laboratory managers and supervisors, who share the responsibility to ensure that policies, rules, procedures, directives, goals and guidelines adopted by the CLD are implemented, understood and practiced by all employees. In addition, the Bureau Standards and Accountability Section, which includes the Quality Assurance Manager, the Quality Process Manager, the Laboratory Accreditation Manager, and the DNA Technical Leader, have key roles in the Division operations, having quality oversight of the Division work. The CODIS Administrator is also considered a key position. All technical leads (Forensic Scientist 4 positions) and the DNA Technical Leader are regarded as technical management and have key roles in our technical operations.

6.1 CRIME LAB DIVISION Commander

This position is responsible for managing all aspects of the Crime Laboratory Division with respect to its operation, organization, policy, and budget.

6.1.1 The CLD Commander:

- Prepares the legislative budget
- Coordinates operation of crime laboratories with other criminal justice agencies
- Define the areas of management authority and responsibility
- Is responsible to ensure that all policies, rules, procedures, directives, goals and guidelines are written in a clear manner, are consistent with Department Policy, state and federal Law, and are made available to division laboratories
- Translates policy into goals, objectives, and strategies, and projects a shared vision of the future to all employees.
- Ensures the Division's operational objectives are achieved
- Ensures resources are utilized to their maximum effectiveness and all programs are providing the most effective and timely service
- Ensure that all employees recognize and support the Division's Quality Assurance Program
- Supervises and trains Division management personnel
- As the CLD appointing authority, authorizes all hiring

6.2 LABORATORY MANAGER

Laboratory Managers, who manage and operate the CLD Crime Laboratories, are responsible for overseeing, monitoring and ensuring compliance to the Quality Management System. In this respect, they function as quality assurance managers for their individual laboratories.

6.2.1 The Laboratory Manager:

- Is accountable for overall forensic operations within a given laboratory
- Provides clear direction and expectations to employees in the laboratory
- Works collectively with other CLD Laboratory Managers and Supervisors, the CLD Commander, and the Standards and Accountability Section to ensure operations are coordinated on a statewide basis as a single system culture
- Assists the CLD Commander in developing and implementing division-wide policies and procedures
- Exercises control over discretionary funds for laboratory supplies, overtime, and training
- Works with employees under their supervision to resolve complaints
- Administers discipline to subordinates as appropriate
- Ensures the effective application of the Division's Quality Assurance Program and is responsible for the quality of the operations for their laboratory
- Ensures the personnel under their supervision receive appropriate training

The CLD Commander will assign CLD Managers to act as Management Liaison for one or more of the following functional areas: Materials Analysis, DNA, Latent Prints, Firearms, Questioned Documents, Crime Scene Response, and Administration. In addition to duties associated with local crime laboratory management, Management Liaisons will have additional duties pertaining to the operation of the functional area throughout the division, to include:

- Develops and updates effective plans to address program direction, staffing, training, equipment, and quality assurance needs within the discipline
- Represents the needs of the functional area to division management, and acts as a conduit between the functional area forensic scientists and division management
- Ensures supervisory and functional area meetings are held and records of meetings are kept
- Works with the functional area technical lead(s) and SAS to determine root causes for systemic or laboratory-level technical non-conformities
- Manages training budget for the functional area; ensures training and travel requests are submitted appropriately according to CLD training needs and available resources

- In collaboration with the functional area technical lead(s), reviews technical and training manuals and revisions to verify compliance with the CLD Quality Operations Manual, and ISO requirements
- Facilitates communication within the functional area so that all labs meet division goals and objectives as a single entity
- Reviews and approves functional area-specific research projects

For the DNA discipline, if the Management Liaison is not the DNA Technical Leader, the intent in functional area representation is to have the Management Liaison specialize more in non-technical matters and the DNA Technical leader specialize more in technical matters with some overlap, consultation and coordination.

6.3 CODIS MANAGER

The CODIS manager is the system administrator of the WSP Crime Laboratory Division's Combined DNA Index System (CODIS) network and is responsible for the security of DNA profile data stored in CODIS.

6.3.1 The CODIS Manager:

- Manages and operates the CODIS Laboratory
- Is responsible for the overall quality and security of the DNA data that is entered into CODIS by the six laboratories within the WSP CLD that perform DNA typing
- Monitors the oversight of CODIS computer training and quality assurance data
- Has the authority to suspend or terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured
- Monitors the Convicted Offender Collection Kit distribution program for the collection of reference samples for all individuals convicted of a qualifying offense
- Advises senior management on DNA operations
- Participates in strategic planning
- Participates in obtaining and managing federal grants to assist and improve DNA analysis
- Represents the Crime Laboratory Division at the state and national level

6.4 STANDARDS AND ACCOUNTABILITY SECTION (SAS)

The SAS is responsible for ensuring the overall quality of forensic service and for monitoring compliance with policies and procedures. The Section is responsible for the implementation and operation of the Quality Assurance Program. Any quality issues will also be shared with the responsible laboratory manager. The laboratory

managers report directly to the Standards and Accountability Section Manager (SAS Manager) on all issues regarding the Quality Assurance Program. The SAS Manager has direct access to the highest level of management where decisions are made on laboratory policy and resources.

This SAS is composed of the SAS Manager, Quality Process Manager, Laboratory Accreditation Manager, DNA Technical Leader and support staff.

6.4.1 Standards and Accountability Section Manager:

The Standards and Accountability Section Manager:

- Serves as the CLD Quality Assurance Manager (QA Manager)
- Manages the FLSB Standards and Accountability Section and reports directly to the FLSB Director
- Supervises the Laboratory Accreditation Manager, Quality Process Manager, DNA Technical Leader, Grant Specialist and CLD Public Disclosure Officer positions
- Assists the CLD Commander in developing and implementing division-wide policies and procedures
- As Quality Assurance Manager, gives direction to and provides oversight of the CLD Quality Assurance Program and the Impaired Driving Section Breath Alcohol Testing Program
- Oversees across the division compliance with policies, procedures and accreditation
- Oversees quality audits: reviews and approves final internal quality audit reports
- Selects, trains and evaluates internal auditors
- Schedules and coordinates management system audits
- Evaluates results of management system audits
- Conducts an annual review of the quality management system
- Organizes and coordinates the annual management system review
- Oversees Grant Management
- Oversees FLSB public disclosure
- Oversees the continuous improvement of the management system
- Approves training plans
- Reviews and approves manuscripts for publications and research projects
- Reviews and approves new methodology, technologies and equipment validations/verifications

6.4.2 Quality Process Manager (QPM):

The Quality Process Manager:

- Works to maintain and improve the quality program of the WSP Crime Laboratory Division

- Administers and coordinates the proficiency testing program, including document retention and responses to inquiries from the accrediting body Proficiency Review Committee (PRC)
- Administers and coordinates the interlab technical review program
- Serves as liaison to the WSP Human Resources Division (HRD): oversees the hiring program for the division; leads recruiting and hiring program for CLD staff
- Participates in annual audits of laboratories
- Serves as the Public Information Officer for the Division
- Coordinates and publishes the Customer Newsletter
- Serves on the Bureau Safety Committee as the headquarters representative; assists in the oversight and implementation of the safety program
- Coordinates and monitors content of the FLSB Portal with the FLSB Librarian
- Maintains and issues Quality System documents and records, including all manuals and forms
- May be involved in the review of root cause analysis and corrective actions for nonconformities and inconsistencies in all testing
- Works with Risk Management Division providing documentation of CLD compliance with the Commission on Accreditation for Law Enforcement Agencies (CALEA) criteria
- Conducts annual audits of CLD firearms and drug reference material collections and participates in other quality audit activities as needed

6.4.3 Laboratory Accreditation Manager (LAM)

The Laboratory Accreditation Manager:

- Monitors compliance with and maintains documentation of accreditation standards
- Functions as the point person for interactions with ANAB and all issues pertaining to accreditation for the CLD
- Coordinates and submits ANAB yearly conformance documents for all laboratories
- Works with ANAB to plan for surveillance visits and assessments, including logistics for hotels and in-state travel for assessors
- Devises, in conjunction with laboratory managers, corrective action plans to address nonconformances from surveillance and assessment activities
- Prepares responses to other ANAB inquiries
- Oversees the development and evaluation of revisions of CLD wide manuals for adherence to accreditation standards
- Conducts an annual review of the CLD Manuals
- Schedules and coordinates internal quality audits
- Prepares final internal quality audit reports in coordination with laboratory managers for review and approval by the SAS Manager
- Oversees the corrective action process in all testing

6.5 DNA TECHNICAL LEADER (TL)

The DNA Technical Leader manages the technical operations of the DNA section throughout the Crime Laboratory Division. This individual will be directly responsible for quality issues involving the DNA functional area and will work with the SAS Manager on all quality matters (all documents on reviews, proficiency tests, reanalysis, etc.). The SAS Manager and/or LAM will provide input on corrective actions, recommend changes as necessary for continuous improvement of DNA quality assurance, and receive copies of quality documents relating to quality assurance measures in DNA.

6.5.1 The DNA Technical Leader:

- Ensures all ANAB accreditation requirements are met by the DNA functional area system-wide
- Plans and coordinates external DNA audits
- Ensures compliance with the DNA audit document for the CLD
- Monitors continuing education for the DNA functional area
- Works with the Standards and Accountability Section to develop the Quality Assurance Program for DNA
- Has the authority to stop DNA work if needed when quality issues are identified
- Has oversight and evaluates the validation for new methods
- Has oversight of the CODIS program
- Advises senior management on DNA operations
- Participates in strategic planning
- Participates in obtaining and managing federal grants to assist and improve DNA analysis
- Represents the Crime Laboratory Division at the state and national level
- Is responsible for DNA Grant Management

6.5.2 DNA QA Support Technical Lead Forensic Scientist

- Assists the DNA Technical Leader in various quality assurance duties
- Provides DNA functional area support in the quality assurance processes including the review of proficiency test results, tracking quality variances and participating in audits and assisting with DNA Technical Leader site visits
- Assists in the interpretation of unusual or complex casework including mixture interpretation, kinship and paternity
- Prepares and presents training materials including training in mixture interpretation, use of appropriate stats and for the implementation of new technology.
- Participates in new technology validations and committees.

- Provides support for DNA outsourcing projects including writing technical review protocols, providing training in the protocols, distribution of technical reviews, liaisons with the participants, and keeping all the associated quality and protocol documents up-to-date.
- Provides support for post-conviction DNA testing including the status of in-house and outsourced case requests, liaisons with the participants, provide DNA testing assessments on possible candidate cases and compose declarations as required.
- Reports and provides assistance to the DNA Technical Leader in technical oversight.
- Act as the DNA Technical Leader in his/her absence.

6.5.3 Grant Specialist

The Grant Specialist helps develop and apply budgets and timelines for grant application planning, and logistics for implementation of awards. Additionally, the incumbent prepares orders, competitive procurement drafts and vendor contracts to carry out purchases for goods and services specified in grant awards, and provides assistance in preparing grant progress reports.

6.5.4 Public Disclosure Tracking Coordinator

The Public Disclosure Tracking Coordinator, typically a Forms and Records Analyst, is primarily responsible to coordinate responses to all public disclosure requests for the CLD, to include delivery and distribution of requested records, and tracking disclosure responses.

6.6 CRIME LAB DIVISION PERSONNEL

6.6.1 Forensic Scientists

The Forensic Scientist class series consists of Forensic Scientists 5, 4, 3, 2 and 1, detailed below. The primary functions of forensic scientists generally include:

- Examination and/or collection of evidence
- Analysis of the physical evidence using accepted and validated methods and analytical instrumentation
- Preserving evidence according to laboratory procedures
- Maintaining chain of custody, i.e., documentation establishing the receipt, handling, and disposition of evidence
- Interpreting observations and test results; preparing written opinion reports
- Testifying as an expert witness in courts of law
- Participating in proficiency testing
- Receiving on-going training and professional development

6.6.1.1 Forensic Scientist 5

This position supervises forensic scientists and support staff within a forensic laboratory.

The Forensic Scientist 5 (FS5 or Supervisor):

- Is responsible for the overall daily administration, operation and coordination of activities within an operational unit of the laboratory
- Assigns and directs tasks to be performed by laboratory staff
- Has a working knowledge of all facets of an accredited laboratory
- Ensures the success of the work-unit through effective leadership, proper training of personnel, effective management of resources, as well as, providing a safe working environment
- Is responsible to address operational, personnel and customer issues
- Analyzes case evidence, prepares written reports and testifies in court as required
- Works to ensure the volume and priorities of work are appropriate for the needs of the assigned functional area of the laboratory
- Represents the needs of the local lab functional area to the Management Liaison and, for the DNA functional area specifically, to the DNA Technical Leader
- Supports communication within the functional area to help meet division goals and objectives as a single entity
- Oversees implementation of training plans, verifies that trainees adhere to established training timelines, and verifies that training is conducted to the highest standards
- Seeks feedback from the functional area technical lead(s) (and for DNA, the DNA Technical Leader) regarding technical issues
- Works with the functional area technical lead(s) (and for DNA, the DNA Technical Leader) to develop training plans
- Resolves conflicts between case analyst and technical reviewer when disagreements occur

6.6.1.2 Forensic Scientist 4 (Technical lead)

This position serves as a forensic technical lead in a specific discipline or functional area of forensic science in a crime laboratory. The Technical Leads in the various functional areas are a vital part of the quality assurance program. The CLD Commander will appoint Technical Leads to provide quality assurance program support through technical oversight and leadership in the functional areas. In the CODIS Laboratory, the FS5 (supervisor) assumes the duties of the Technical Lead.

The Forensic Scientist 4 (FS4):

- Performs complex analyses on physical evidence. This involves casework where applied research, method modification, or a unique approach may be necessary; or a single definite conclusion is not possible and a weighted conclusion is warranted; or casework requiring the reconstruction of an event or series of events based upon the interpretation of physical evidence
- Works with the Standards and Accountability Section in the performance of their assigned quality assurance duties
- Is accountable for the quality of the casework product, for compliance with all applicable accreditation and audit criteria, compliance documentation, validation of new technology and methods, and investigation of casework nonconformances
- Has responsibility for uniform methodology implementation and use in all laboratories within the discipline and responsibility for evaluating all methods used
- Has the responsibility to oversee standard training for new employees, and re-training of existing employees as needed in conjunction with the employee's supervisor, within the discipline
- Has the responsibility to see that quality practices are utilized in all scientific equipment maintenance, and ensure appropriate quality control is implemented within the discipline
- Ensures that procedures and training manuals for the discipline accurately reflect established standards and comply with accreditation requirements
- Evaluates new analytical procedures, equipment or technologies, oversees their validation and assists with implementation
- Reviews proposed research projects
- Assists in coordination, content, and execution of the Functional Area Meetings to include setting up training workshops in conjunction with the FAM
- Supports communication within the functional area that helps all labs meet division goals and objectives as a single entity
- Conducts regular site visits to laboratories in the division to provide one-on-one mentoring of functional area scientists
- Ensure methodologies are in compliance with health and safety requirements
- Assists supervisors with resolving disagreements between case analysts and technical reviewers, resolving other technical issues, and assists Standards and Accountability with root cause analysis involving technical nonconformities
- Has the responsibility to recommend the termination of testing in their discipline in the event of a technical problem with a technical procedure, instrumentation or equipment. Communication of such action must follow the appropriate chain of command.

6.6.1.3 Forensic Scientist 3

This is the senior level of the Forensic Scientist series.

The Forensic Scientist 3 (FS3):

- Scientifically analyzes evidence in routine, non-routine and complex casework in an area(s) in which they have been authorized and are proficient and productive. Complex analysis involves casework where applied research, method modification, or a unique approach may be necessary; or a single definite conclusion is not possible and weighted conclusion is warranted; or casework requiring the reconstruction of an event or series of events based on the interpretation of physical evidence. Databasing scientists develop DNA profiles from convicted offenders for inclusion in the Combined DNA Index System (CODIS).
- Formulates sound conclusions from data without exceeding the boundaries of the data. Data may result from complex analyses involving multiple methods and techniques, multiple items and examinations
- Reports scientific findings in the form of a written forensic laboratory report based on the interpretation of observations and analytical test results
- Completes analyses of high quality, performed using forensically accepted scientific methods, and in accordance with the CLD Quality Operations Manual and the Section Technical Procedures Manual
- Documents and protects evidence according to laboratory procedures, ensuring that the chain of custody is maintained
- Provides technical review and administrative review
- Abides by accreditation criteria
- Testifies as an expert in courts of law

6.6.1.4 Forensic Scientist 2

This is the journey level of the series.

The Forensic Scientist 2 (FS2):

- Will have completed the majority of their training in an assigned discipline and will focus on the routine analysis of physical evidence. Routine analysis involves laboratory examination in which the items to be tested require a single specific examination or a standard battery of examinations or analyses, the results of which lead to a conclusion acceptable to experts in the field. Databasing scientists develop DNA profiles from convicted offenders for inclusion in the Combined DNA Index System (CODIS)
- Formulates sound conclusions from data without exceeding the boundaries of the data
- Reports scientific findings in the form of a written forensic laboratory report based on the interpretation of observations and analytical test results

- Completes analyses of high quality, performed using forensically accepted scientific methods, and in accordance with the CLD Quality Operations Manual and the Section Technical Procedures Manual
- Documents and protects evidence according to laboratory procedures, ensuring that the chain of custody is maintained
- Provides technical review and administrative review
- Abides by accreditation criteria
- Testifies as an expert in courts of law

6.6.1.5 Forensic Scientist 1

This is the entry level of the series.

The Forensic Scientist 1 (FS1):

- Works in a training capacity and under close supervision
- Performs beginning level analyses of physical evidence in criminal cases submitted to the forensic laboratory. Databasing scientists develop DNA profiles from convicted offenders for inclusion in the Combined DNA Index System (CODIS)
- Interprets analytical results, prepares written opinion reports, and testifies as an expert witness in courts of law
- With on-the-job training, the incumbent learns entry-level casework in a limited area in order to become proficient in a discipline of forensic science
- Abides by accreditation criteria

6.7 TECHNICAL SUPPORT STAFF

6.7.1 Laboratory Technician

The Lab Technician performs routine tasks following clearly defined laboratory procedures, performs quality control measures and operates routine laboratory equipment. The Lab Technician may or may not be proficiency tested depending upon their assignment.

6.8 ADMINISTRATIVE STAFF

6.8.1 Property and Evidence Custodians

The Property and Evidence Custodian (PEC) receives evidence into custody from law enforcement agencies and releases evidence back to the submitting agency upon completion of analysis. They maintain the appropriate records of evidence transactions using the Laboratory Information Management System (LIMS). They also conduct periodic inventories and audits of evidence depositories. In addition, in some laboratories they may be responsible for general office and clerical duties, including ordering supplies, preparing pay documents, report preparation and filing as required by their supervisor. PECs may be required to testify in court.

6.8.2 Office Manager

The Office Manager (OM) plans, organizes, assigns, and supervises varied and extensive processing and service units and related central office activities, including evidence handling.

6.8.3 Administrative Assistant

The Administrative Assistant (AA) performs a variety of complex clerical duties in support of office and CLD operations.

6.8.4 Office Assistant

The Office Assistant (OA) performs a variety of routine clerical duties in support of office or unit operations.

6.8.5 Trooper Cadet

Occasionally trooper cadets may be assigned to a laboratory to assist with administrative tasks and functions. These positions are temporary with the availability of cadets depending on the needs of the Agency.

6.8.6 Volunteers and Interns

Volunteers and interns may participate in research projects, data and reference materials collection, or other projects suitable to their knowledge, skills and abilities, but may not work directly on casework. A volunteer is a non-paid position: an intern may be either a paid or a non-paid position. Prior to beginning work in the crime lab, all volunteers and interns are required to submit to and pass a polygraph test and background investigation.

7 PERSONNEL QUALIFICATIONS AND TRAINING

7.1 POLICY

The Division will ensure that personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills.

7.2 QUALIFICATIONS OF PERSONNEL

All personnel assigned to or contracted by the WSP CLD must be competent, trained and supervised to ensure that they conduct work according to the quality program of the CLD (ISO 5.2.3). It is the responsibility of the laboratory manager to demonstrate the competence of all staff, whether directly employed or contracted. There must be documented evidence of the training and qualifications for all staff.

A Position Description Form (form OFM 12-002 WGS, hereafter PDF) shall be completed for all CLD employees. The PDF shall be retained in the employee's supervisory desk file and shall be updated as necessary. The PDF includes minimum education and experience requirements for laboratory management, technical management and staff according to their respective positions.

When an individual under contract is conducting casework for the CLD, the supervisor or laboratory manager will advise the customer in writing of the subcontracting arrangement and will gain approval from the customer, preferably in writing. Communication to the customer regarding the transfer or referral of casework to another WSP laboratory is not required. Convicted offender DNA samples may be examined by contract personnel without pre-approval from the collecting agency.

7.3 EDUCATIONAL BACKGROUND

Educational requirements for CLD technical positions are found on the Washington State Office of Financial Management website. The PDF includes educational requirements for each position. Verification of educational requirements for staff is under the purview of the Washington State Department of Enterprise Services (DES) and WSP Human Resource Division (HRD). The QP Manager will ensure that college transcripts of all employees are reviewed before employment. Transcripts are typically retained at the employee's laboratory or at HRD. Copies of transcripts for those scientists performing casework in the DNA unit and CODIS are located in the employee's assigned laboratory. Educational background and training history for technical personnel should be updated annually on a Statement of Qualifications prior to external assessments and on-site or off-site surveillance.

7.4 HIRING PERSONNEL

All employees shall be hired according to rules that govern their position. The supervisor and the laboratory manager of the position to be filled shall be involved in the hiring process. The CLD Commander has appointing authority and makes the final decision on hiring new employees.

7.5 PERSONNEL TRAINING AND DEVELOPMENT

CLD Management will ensure that proper training occurs for all CLD staff. Laboratory managers will ensure that employees meet and maintain competency requirements. In addition, each employee will share in the responsibility of maintaining his/her functional area discipline expertise and competency.

7.5.1 Training and Development Goals

Training goals include:

- Basic functional area competency
- Maintenance of acquired skills and abilities
- Instruction in new and improved techniques
- Acquiring and maintaining professional accreditation or certification
- Application of ethical practices in forensic sciences, a general knowledge of forensic science, and applicable criminal and civil law and procedures
- Meeting agency requirements for mandatory training and policy awareness
- Where applicable, training in the presentation of evidence in court
- Training in ethics and professional behavior expectations

7.5.2 Training and Development Opportunities

Various types of training and employee development opportunities are available for CLD employees including, but not limited to:

- CLD personnel experienced in a variety of forensic analyses and processes
- CLD functional area in-service training
- CLD sponsored forensic training courses utilizing visiting experts
- WSP sponsored training
- Workshops and seminars
- State educational and career development resources
- Continuing education opportunities available through universities and community colleges
- Agencies and institutions such as the FBI, National Forensic Science Technology Center, National Institute of Justice, California Criminalistics Institute, Bureau of Alcohol, Tobacco and Firearms, Washington Criminal Justice Training Commission, and others

- Professional forensic science organizations such as the American Academy of Forensic Sciences, the Northwest Association of Forensic Scientists, the Association of Firearm and Tool Mark Examiners, and others
- Journals of professional forensic science organizations and other scientific literature

The CLD will periodically provide discipline in-service training opportunities at Functional Area Meetings for the purpose of exchanging technical information on novel discipline procedures, techniques, and/or research developments. Such in-service meetings will occur at least annually for Forensic Scientists and Property and Evidence Custodians and are aimed at scientific advancement, process improvement, solving technical problems, and identification of relevant training needs and opportunities. These goals support the continuing professional development and maintenance of competency of individual employees which in turn support the overall competency of the CLD programs. The CLD will support the functional area meetings and endeavor to act on recommendations when possible.

The CLD will provide support to employees who wish to pursue personal certification through a relevant professional organization. The laboratory manager may provide some work time for study and preparation. The cost of the initial application, testing fees, and subsequent maintenance fees are the responsibility of the individual employee.

Attendance at conferences and workshops sponsored by professional forensic organizations is an effective way for employees to stay current in their field. This venue provides a significant source of continuing education that directly supports their professional development and maintenance of competency. Serving as members or officers of these organizations facilitates employees staying in contact with their peers across the nation, a process vital to scientific advancement. In order to achieve these goals, the CLD will provide membership in two relevant professional forensic organizations for each forensic scientist. The CLD will endeavor to send at least one scientist to each of the annual conferences sponsored by the major professional forensic organizations with a level of financial support consistent with current resources.

7.6 TRAINING PROGRAM

7.6.1 Policy

The CLD will have a documented training program to include new employee training, training in a new discipline, retraining and continuing education for maintaining skills and expertise. Prior to being authorized to perform assigned duties, trainees will successfully complete the applicable training program. The effectiveness of the training program shall be evaluated (ISO 5.2.2).

All technical and technical support staff, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test prior to assuming casework responsibility in the laboratory. Crime Scene personnel shall satisfactorily complete a competency test prior to assuming primary responsibility for the examination, documentation and processing of a crime scene.

Qualified analysts who have been absent from laboratory casework such that they are taken out of the proficiency test cycle, must be assessed prior to resuming casework. The assessment of the analyst's current analytical capacity for a given type of casework may involve completion of manual reviews, retraining and competency testing. The assessment plan must be approved by the Lab Manager and if it involves DNA, the DNA Technical Leader. Successful completion of the assessment must be documented and approved by the CLD Commander.

Each laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This responsibility lies primarily with supervisors, but individual scientists are strongly encouraged to maintain copies of their own training records. The records to be maintained include documentation of completion of specific training modules as appropriate, successful completion of written tests, summaries of oral tests and responses, competency tests and associated reports. This information shall be readily available for review by an assessor and shall include the date on which authorization and/or competence is confirmed.

Training records will be sufficiently detailed to provide evidence that employees have been properly trained and that their ability to perform the task of their specific discipline has been assessed.

Training needs of an employee will be identified through individualized training plans and goals, CLD strategic plans, management requests and needs of the customer agency.

7.6.2 Trainer/Trainee Method

The CLD employs the trainer/trainee method as one component in teaching for technical discipline training and training in a new job classification. The trainer and trainee will have management commitment and resources to provide a quality training experience. Training may take place at sites other than the trainee's assigned laboratory.

7.6.3 Trainer

Trainers have the responsibility for ensuring the trainee successfully completes the training plan. The trainer will be selected by the supervisor, Technical Lead and/or lab manager and should have the following abilities:

- Have an understanding of WSP and CLD structure, policies, and procedures.
- Have an understanding and working knowledge of the current procedures, requirements, and expectations for the given functional area or discipline
- Ability to instruct and train based on the training manual for the given discipline
- Ability to offer constructive criticism and positive reinforcement that is crucial to the trainee's learning process
- Ability to interact routinely, frequently, and one-on-one with the trainee (s) to assess their understanding and mastery of the subject matter
- Ability to record the trainees' progress with evaluations per CLD and/or functional area requirements and routinely report on progress through the chain of command.
- Good organizational, verbal and written skills
- It is expected that senior level staff be able to serve as trainers in their functional area. Journey level staff may additionally assist with training as appropriate.

7.6.4 Competency Test

A competency test is the final examination provided to a trainee at the end of training modules or at the end of the training plan for a specific functional area discipline. The competency test results are evaluated by the assigned trainer and lab supervisor of the discipline. For any laboratory personnel whose job responsibility includes casework testing, performing specific tasks that create items that could be used for testing, test report writing, or testimony, competency tests shall include, at a minimum:

- Examination of sufficient unknown samples to cover the anticipated spectrum of assigned duties and evaluate the individual's ability to perform proper testing methods;
- A written report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of those results/conclusions; and
- A written or oral examination to assess the individual's knowledge of the discipline, category of testing, or task being performed. For testimony competencies, a written examination is not sufficient to demonstrate competency: an oral presentation is required.
- If testimony is within the anticipated work of the individual, a written evaluation conducted by a technically competent reviewer of the individual's ability to provide testimony must be completed.

7.6.5 Training Manual

A training manual outlines the necessary requirements to become competent in a forensic discipline or functional area. The training manual is designed to provide employees with an understanding of theory and principles, application,

methodology, technical limitations, and equipment involved in the functional area. The manual is further intended to provide the trainee with a sufficient understanding and skill level to satisfactorily conduct independent casework examination in the forensic discipline or category of testing. It includes modules or sections of reading assignments, study/discussion questions, and practical exercises. The technical procedures or training manuals will contain the approved methods, the scientific references and resources, and the requirements for successfully completing a training program for each discipline.

Training manuals for each functional area will provide a detailed training outline for new and permanent employees. These training manuals will also be used as a guide when designing job performance improvement plans.

7.6.6 Training Plans

Supervisors will work with each employee to develop a training plan. In developing the training plan, the supervisor must consider the needs of the individual employee, the discipline, the CLD and the customer agencies.

Training plans developed for each functional area will be used for developing new employees. Training shall include the application of ethical practices in forensic sciences, a general knowledge of forensic science, testimony and applicable criminal and civil law and procedures. All training modules included in an employee's training plan will have clearly defined goals for successful completion which are measurable in order to document progress and achievement of intended results. Measurement tools will normally include, but are not limited to, scored examinations and competency tests where pass and fail is defined.

If supervised casework is required in the training plan (this is not a requirement in all disciplines and may not be required for all training plans within a discipline), the number and type of cases shall be specified in the training plan. Competency testing for the testing being supervised must have already been successfully completed prior to supervised casework.

The training plan will be updated annually during the employee's performance evaluation and may be adjusted as needed throughout the year. Supervisors must be actively involved in the employees' training, including documenting training events and training performance in the employee's supervisory desk file.

An employee adding or transitioning from one technology to another within the same functional area will undergo appropriate training from a developed training plan, followed by a competency test to ensure that they have demonstrated proficiency in that technology. For a newly validated method in the DNA Functional Area, a competency test may be waived by the DNA Technical Leader for those who have demonstrated their necessary competency in validation study work.

7.7 RE-TRAINING

Re-training in a given discipline may be required when:

- Employees who were once qualified in the discipline or functional area but have not maintained the required competency in that discipline or functional area
- Qualified analysts who, because of leave or other circumstances, are unable to complete a proficiency test in their discipline in a calendar year
- Employees who were previously qualified at another laboratory system (non-WSP) in the particular functional area
- A discipline's procedure or training manual, in the judgment of the functional area supervisors and technical leads, has been revised to the extent that re-training is necessary.
- Directed by a corrective action plan (CAP), job performance improvement plan (JPIP) and/or remedial training
- Required by administrative rule

Re-training will include an evaluation of current knowledge and skills by the supervisor in consultation with technical lead(s) familiar with the sub-disciplines required, and the laboratory manager. A training plan will be prepared and approved by those involved in the evaluation and will include, as needed, any reading, remedial training modules, and written tests deemed necessary. Successful completion of competency testing will be required before resuming casework.

7.8 TRAINING PROGRAM PROCEDURES

The following steps will be followed to ensure successful completion of the training program:

- Assign Trainer: The trainee will work under the direction of a trainer, who is assigned by the Technical Leader, supervisor, and/or lab manager.
- Develop Training Plan: The supervisor and/or technical leader will develop a comprehensive training plan for each new employee with estimated timelines. This comprehensive plan will include the functional area specific training plan(s). Modified training plans will require approval from the Laboratory Manager, the Quality Assurance Manager, and for DNA and CODIS, the DNA Technical Leader. Training plans may also be developed for journey level employees as required.
- The trainee will work with the assigned trainer and instructors to successfully complete the training plan. Completion of the required training elements will be documented by both the trainee and the trainer. The trainee's supervisor will be notified of successful completion of the training plan.

- In certain areas it is necessary for trainees to get experience looking at and working with real world casework samples in order for them to gain the necessary knowledge and skill to become competent in that area. Some examples are microscopic comparisons of bullets, comparison of latent print evidence, questioned document examinations and various microanalysis procedures. In these areas, the examination of casework evidence by a trainee is permitted if the examination is overseen by a qualified Forensic Scientist, the examination is non-destructive and will not alter the evidence, and the trainee has completed applicable competency testing for that task prior to examination of casework evidence. The examination of the casework samples is purely for training purposes. The original analyst on the case will review the trainee's documentation and provide feedback on the examinations. Additionally, the original casework analyst will ensure all of the evidence has been properly sealed and is ready for return to the submitting agency.
- Training Evaluations: During the period of training, training evaluations will be completed and documented by the trainer. The results of these evaluations will be discussed with both the trainee and the supervisor of the trainee. Progress on training will be reported monthly to the laboratory manager until the training concludes. Copies will be forwarded to the Standards and Accountability Section as requested.
- Mock Case Samples: During training, the analyst may be provided mock case samples in which he/she can gain experience in case management, case file preparation, and report writing. The number and type of mock cases will be determined by the trainers and documented in the training plan.
- Competency Tests: The supervisor and/or technical lead will be responsible for administering competency tests. The competency tests must be successfully completed by the trainee prior to the start of casework. The results will be maintained as part of the training record.
- Moot Court: Trainees whose duties anticipate providing testimony will participate in moot court prior to performing testing or performing specific tasks that create items that could be used for testing. Evaluations and feedback from the participants will be provided to the trainee and the supervisor.
- Training Records: Training records of the trainee will be retained by the trainee and/or supervisor.
- Approval to Conduct Forensic Analysis (or to perform specific tasks that create items that could be used for testing): The trainee must demonstrate the successful completion of the training plan by passing all examinations and competency tests that are part of the training plan. Upon successful completion of either training modules or the final training plan, an IOC will be submitted through the chain of command to the Division Commander for final approval before the trainee can begin work in that defined area. The

approval documentation for a scientist in DNA or CODIS must also include the DNA Technical Leader. A copy of the final approval will be given to the Quality Assurance Manager. The analyst will be authorized to perform work in only those areas in which he/she was approved.

- Once approved for analytical work, the analyst may be required to perform supervised casework in accordance with the applicable functional area training and/or technical procedures manual. Supervised casework reports completed by the analyst will be signed by the analyst. The scientist monitoring the casework will sign, or initial, and date the draft report. The casework would then go through the normal technical and administrative reviews, with the scientist monitoring the casework being excluded from the technical review.
- Approval to Perform Technical Review: Authorization to perform technical review of other analysts' casework must be documented in an IOC. This may be included within the IOC documenting the successful completion of the analyst's training plan, or a separate IOC. If a separate IOC is issued, it will be submitted through the chain of command, with final approval by the Laboratory Manager. The approval documentation for a scientist in DNA or CODIS must also include the DNA Technical Leader. A copy of the authorization to conduct technical review will be provided to the Quality Assurance Manager. Supervisors will be responsible to assign reviews commensurate with the analyst's experience.
- Concluding the Training Process: At the conclusion of the training program, the effectiveness of the training program shall be evaluated by the trainer, appropriate technical lead and/or trainee based on the trainee's performance on written exams, competency tests, practical exercises, and/or mock trial results. Improvements to the program are made as needed and the review is documented through the annual review of controlled documents.

7.9 REQUESTS FOR TRAINING

Refer to WSP Regulation Manual 10.12.020 TRAINING DIVISION for instructions on completing a Training/Travel Request (WSP Form 3000-320-016). Training requests incurring costs and specific to a functional area will be routed through the chain of command and include the Management Liaison. All training requests will be approved or denied within thirty (30) calendar days from the submission of a properly completed request. If a request is denied, the person denying the request will provide a reason for the denial to the employee.

Employees engaged in their planned training program in their laboratory generally do not need to submit Training/Travel Requests (TTR) for the training modules in their program unless the above conditions apply. All training/travel events incurring costs will be documented on the CLD Training Spreadsheet.

7.10 COMPLETION OF TRAINING

Refer to WSP Regulation Manual 10.12.020 TRAINING DIVISION for instructions on submitting a Report of Training using the TTR form. In addition, a Report of Training must be completed for training received at functional area meetings. The completed form must be routed through the supervisor and then appropriately routed for entering the information into the employee training records by the local eTrain user or Administrator. Copies of all training and continuing education records for completed training will be maintained at the employee's laboratory. An electronic version of each employee's training records is maintained indefinitely in the Washington State Patrol eTrain program. It is recommended that employees maintain their own training records for career planning, performance appraisals, individual certification, and other uses.

7.11 REQUESTS FOR TRAVEL

Refer to WSP Travel Regulations for information on completing a Training/Travel Request (WSP Form 3000-320-016).

7.12 LABORATORY LIBRARY

Each laboratory will have access to a library containing current books, journals, and reference materials for each discipline. Each analyst is responsible for taking time to read periodicals, journals, articles, books, and laboratory memorandums in order to keep current with information and developments in their respective disciplines. A list of the contents in each library is maintained by the FLSB Librarian. The FLSB Librarian distributes by email the table of contents of various journals, magazines and publications. The FLSB Librarian is a resource for obtaining journal articles and other needed reference material and should be contacted when necessary. These may also be found on the FLSB Portal.

7.13 COURTROOM TESTIMONY TRAINING

CLD management is responsible for ensuring that testimony training is provided to employees who testify in court. Topics such as evidence handling, chain of custody, casework results and interpretation of examination or test results should be discussed during the training. Property and Evidence Custodians should also be given courtroom testimony training regarding evidence handling and chain of custody. This training can be given internally by a CLD employee or by an external source. Documentation will be maintained for each individual with their regular training records.

7.14 JOB PERFORMANCE

7.14.1 Documenting Job Performance

Supervisors will document the work performance of each employee they supervise and maintain those records in a supervisory desk file. Supervisory desk files will contain positive and/or negative supporting documents, counseling, work directives, evaluations, or records relating to an employee's job performance throughout the performance period. Supervisory desk files are required to be purged each year following an annual evaluation; training records will be maintained separately.

Employees will have access to and be made aware of the contents of the Supervisory Desk File. (See the Collective Bargaining Agreement.) Annual performance appraisals are required and will be completed for each employee.

8 DOCUMENT CONTROL POLICY AND PROCEDURES

8.1 POLICY

Documents that form the CLD Management System are controlled to ensure that only current, up-to-date documents are being used. All CLD management system documents will be made available to CLD staff via the FLSB Portal. The following procedure provides instructions concerning the creation, revision and distribution of these controlled documents. WSP agency documents are controlled and distributed by the agency.

8.2 DEFINITIONS

8.2.1 Document

A document is any writing or other item that conveys information in any medium including, but not limited to, paper copy, electronic file, audio or videotape, or photograph.

8.2.2 Document Control

Document control is the process for ensuring that controlled documents, including revisions, are reviewed, approved and released by authorized personnel (Issuing Authority), and distributed to personnel performing the prescribed activities.

8.2.3 Controlled Document

A controlled document is any document that forms a part of the CLD management system, and is subject to the requirements of this document control policy. Examples of controlled documents include policy, procedure, technical and training manuals, and required-use forms.

8.2.4 Document Review and Approval (DRA) Form

Document Review and Approval Form, used for all proposed modifications to controlled documents.

8.2.5 Form

A form is a printed, typed or electronic document with blank spaces for insertion of required or requested information. When required for use by policy or procedure, forms will be controlled documents. Adding lines, rows, columns or spaces are allowed as needed, provided the additions maintain the format and integrity of the form (such as retaining column/row headings when adding columns/rows).

8.2.6 Worksheet

A worksheet is a printed, typed or electronic document with blank spaces for insertion of required or requested information. Worksheets may be used to assist in collecting and recording information in casework, and are part of the case record.

When used for convenience but not required, worksheets need not be controlled. When required for use by policy or procedure, worksheets become controlled forms.

8.2.7 Record

Documents, including logs, forms, worksheets and electronic files that provide support of conformity to the quality management system. They may be held in the individual laboratories or at CLD Headquarters. These documents include, but are not limited to, method and equipment validation documents, equipment verification records, reagent and chemical QC logs, training records, proficiency test records, courtroom testimony monitoring records and audit records.

8.2.8 Uncontrolled Copy

A copy of a controlled document provided for informational purposes only. Examples include copies provided to external inspectors or copies required for legal discovery.

8.2.9 Issuing Authority

Personnel that are authorized to approve the posting of controlled documents on the FLSB Portal. The issuing authority for Bureau-wide controlled documents is the Bureau Director. For Division-wide documents, it is the Division Commander. The issuing authority for laboratory-specific policies and procedures is the Laboratory Manager.

8.2.10 Master Document List

An electronic file maintained by the Quality Process Manager and available to all employees via FLSB Portal which contains the current revision status of any controlled document.

8.3 PROCEDURE

8.3.1 Controlled Document Format

Each controlled document will have the following format requirements:

- A header on each page containing, at a minimum:
    - Washington State Patrol Crime Laboratory Division
- A footer on each page containing at a minimum:
    - Page _ of _
    - A statement indicating that “All Printed Copies are Uncontrolled”
    - The unique document identification
    - Revision number and revision date
- Controlled forms do not require the “All Printed Copies are Uncontrolled” statement, as they are intended to serve as a template for entering data or

information. No modifications to the form, except as noted in the above definition, are allowed without going through the document revision process.

Revision number indicates the total number of times the document has been revised since adoption of original document.

All controlled documents will have a history table indicating when the document was originally adopted and any revisions that have occurred since date of adoption. The table will include the following:

- Document Name
- Revision Number
- Date of Revision

This history table for each controlled document will be maintained on the FLSB Portal and will be updated with each revision. The master document file shall be maintained by the Quality Process Manager and will be available to all employees via the FLSB Portal, listing all the current approved documents.

8.3.2 Controlled Document Preparation

Documents should be prepared by personnel with adequate expertise in the subject. The detail of the document should be commensurate with the complexity of the activity and the background of the intended user of the document. The document must include enough detail and specificity to ensure that the activity conforms to quality specifications and/or expectations.

Recommended changes must represent the objectives of the CLD and not conflict with the WSP Regulation Manual, Revised Code of Washington, or Washington Administrative Code. Laboratory specific policies and procedures cannot supersede the CLD Quality Operations Manual. All affected members of the CLD should have the opportunity to provide input on the proposed changes prior to submission.

The preparer of the new or revised document is responsible for:

- Preparing the document in the proper format
- Acquiring copies of listed references
- Addressing or resolving comments from reviewers
- Submitting for review and approvals using the Document Review and Approval Form.

All proposed revisions must be submitted on form 4002, Document Review and Approval (DRA). The following information must be provided:

- The manual/controlled document name and the specific section of the manual/controlled document to be modified, or the proposed new document or section;

- A statement briefly describing the need for the procedure modification or incorporation of a new procedure.

Proposed changes should be clearly marked and submitted as an edited version tracking all changes made to the current document as follows:

- Deleted portions will have a strikeout
- Additions will be highlighted in yellow
- "Track changes" can be used as an alternative

Amendment of documents by hand pending the electronic re-issue of the revised controlled document is not allowed.

Note: Typographical or grammatical errors do not require a DRA. These types of errors will be brought to the attention of the Quality Process Manager for correction.

8.3.3 Controlled Document Review

Review is required for each new or revised controlled document prior to approval. For DRA's unrelated to technical manuals/forms, the DRA will be reviewed through the supervisor and laboratory manager. For changes to technical manuals/forms, the Functional Area Supervisors, Technical Leads, DNA Technical Leader and/or Management Liaison will be responsible to ensure that the recommended changes represent the accepted body of scientific knowledge, both internal and external to the CLD. Technical review is for accuracy and clarity. The reviewer(s) must have adequate technical expertise in the discipline to evaluate the document.

A quality review is conducted by the SAS to ensure that the document conforms to accreditation and quality standards.

8.3.4 Controlled Document Approval

Each controlled document issued will be approved through the review process outlined above, with final approval authority by the SAS Manager. All DNA and CODIS documents will be approved through the DNA Technical Leader. Review and approval of controlled documents are recorded on the DRA.

8.3.5 Controlled Document Issue

After the documents are approved, the document will be issued through the QPM. The approved controlled document will be posted on the FLSB Portal and CLD management will be notified by the QPM via e-mail. The notification will include the DRA, effective date, and affected staff. Lab management will be responsible for notifying affected staff and ensuring email acknowledgement of review and receipt is completed. In lieu of email acknowledgement, a Document Control Sheet (DCS) may also be completed. The next revision of the entire manual will include the approved changes from this procedure and will be posted on the FLSB Portal.

Once a document is adopted, it will be the responsibility of laboratory management to ensure it is implemented. Lab managers will be responsible for maintaining the DCS, or email acknowledgement, which will be subject to the audit process.

If a recently approved DRA needs to be altered within a very short time frame after being posted, the QPM can make the necessary changes and document on the approved DRA the sections which were modified. The QPM will be responsible for notifying staff of these changes or if a new DRA is required.

The document history will note the changes as described above and include the date of the entire revision. All personnel will have access to the official electronic documents. However, administrative access to the official electronic controlled documents will be restricted to prohibit unauthorized changes.

8.3.6 Archiving Controlled Documents

Obsolete documents will be archived on the "Archived Manual" section of the FLSB Portal. The date that a document is removed from active status and placed into "archived manuals" will be recorded on the specific document. The labeling of a document with this "archived date" will be used to denote that a document has been officially placed in archived status.

Employees shall use current versions of approved documents. Invalid or obsolete documents shall be promptly removed from all points of issue or use, or otherwise assured against unintended use; obsolete documents retained for either legal or knowledge preservation purposes shall be suitably marked.

8.3.7 Annual Review of Controlled Documents

Controlled documents will be annually reviewed and revised if needed to ensure they reflect current policies, practices, and technology. The revised documents are subject to the same review, approval, documentation and issuance requirements of the original document as stated above.

Technical leads and supervisors or the DNA Technical Leader will conduct this review for their respective technical and training manuals and forms. The Standards and Accountability Section will review administrative manuals. Laboratory managers will review their individual local lab policies. Documentation of this review will be by an IOC from the reviewer to the QPM, who will record the review on the document history table.

8.3.8 Official Controlled Documents

The official controlled documents to be used by personnel are those posted on the FLSB Portal. All employees will have access to this site. Any copies of documents from this site represent unofficial copies and will be designated as such. The Quality Process Manager or designee will maintain the official controlled documents and archived versions of all controlled documents on the FLSB Portal.

8.3.9 Returned

Any DRAs submitted to the SAS that need to be returned, will be accompanied by a written explanation and/or suggestion for modification.

8.3.10 Tabled

Any DRAs submitted to the SAS that need to be tabled, will be accompanied by a written explanation along with the estimated date for reconsideration if applicable.

8.3.11 Submission of Requests for LIMS Manual Revisions

Recommended changes to the LIMS Manual are made using the same process noted above for document revisions, but are additionally routed through the Administrative Management Liaison.

9 QUALITY SYSTEM RECORDS: ACCESS, FILING, STORAGE, RETENTION AND DISPOSAL

Quality system records are any logs, worksheets, electronic files, spreadsheets or databases that provide documented support of conformity to the Quality Management System. These records include, but are not limited to:

- Method validation documents
- Equipment repair and verification records
- Reagent and chemical QC logs
- Training records
- Proficiency and competency test records
- Courtroom testimony monitoring records
- Chemical inventory records
- Reference collection records
- Audit records

These records are maintained by the CLD staff. Filing, storage and retention of these records are as described below. Access to those records maintained at CLD Headquarters is given to the CLD Commander, the Standards and Accountability Section staff, lab managers, auditors, and supervisors for information pertaining to their respective assignments and responsibilities. Individuals may request copies of quality documentation pertaining to themselves. There may be overlap between records held at CLD Headquarters and the individual labs.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.

Records stored electronically shall be stored as to prevent unauthorized access or amendment, and will be routinely backed up to prevent loss.

9.1 RECORDS FILED, STORED AND RETAINED AT CLD HEADQUARTERS BY THE STANDARDS AND ACCOUNTABILITY SECTION

- Training completion records
- Proficiency test answer sheets
- Method validation approvals
- Corrective actions
- Job performance improvement plans
- Policy and Procedure manual document review and approval forms
- Audit records and reports
- Laboratory safety inspection reports
- Official electronic controlled documents

9.2 Records Filed, Stored and Retained at CLD Laboratories

- Appropriate personnel records
- Equipment performance verification, associated equipment method validation and maintenance records will be maintained at the laboratory in close proximity to the equipment (on-site),
- Case files and records, and any associated examination or administrative documentation according to retention schedules
- Records on deviations from procedure
- Chemical and reagent quality control logs and worksheets
- Temperature logs and other Quality Control documentation
- Standards and reference collection inventory records and verification logs
- Chemical Inventory databases
- Key control records
- Equipment Inventory
- Lab facility maintenance and security records and logs
- Safety records
- Courtroom testimony monitoring records
- Visitor logs

9.3 Records Maintained in Division-Wide Databases/Spreadsheets

- Laboratory Library Collection
- Firearms Reference Collection database
- Laboratory Information System (LIMS)
- CLD Vehicle Maintenance Records (maintained in Remedy)

9.4 Archive and Retention of Quality System Records

Retention and disposal of quality records will follow the Washington State Patrol Archive Record Retention Schedule through at least one cycle of accreditation (four years). A current copy of the Archive Retention Schedule may be found on the FLSB Portal.

9.5 Case Records: Filing, Storage, Access, Retention and Disposal

The laboratory will maintain all original case documentation (administrative and examination) in files bearing unique laboratory case numbers. All records shall be legible.

If an original record, paper or other media is captured as an electronic record, and the original record will be destroyed, the laboratory shall ensure that the electronic record is complete prior to destruction of the original record.

9.6 CUSTOMER COMMUNICATIONS

All communications with customers that form the basis for decisions in casework are documented in the case record either in the case notes or in LIMS (case information field). The date, name of contact, and the conversation (in substance) will be recorded.

9.7 STORAGE AND ACCESS

Case records will be stored in a manner that they are readily retrievable and protected from damage, deterioration or loss. Case records may be retained in the case folder as part of the case file, may be in a reagent or instrument log, or may be retained electronically (e.g., LIMS information and digital images). Upon completion, all case files will be stored only in designated areas. No completed case file will be kept in the possession of scientists unless replaced by a sign-out file locator. If case files are removed from the laboratory, for example when going to court, due diligence and caution will be exercised to preserve and protect the file and its contents. The laboratory will protect and make back-ups of case records stored electronically and will secure such records to prevent unauthorized access to or amendment of these case records.

9.8 ARCHIVING

All case files will be maintained under the control of the CLD until they are archived. Each laboratory will maintain a minimum of the previous two years plus current year of case files. Case files older than five years should be sent to the State Records Center for secure storage, unless there are reasons to retain the case files in the lab. Each laboratory maintains records of files that are stored at the State Records Center.

Prior to archival at State Records, the contents of case files will be secured against loss.

9.9 EXPUNGEMENT OF RECORDS

On receipt of a court order for expungement, the Division Secretary at CLD Headquarters should be contacted. Division staff will make any appropriate contacts with the WSP Risk Management Division who will provide guidance to the laboratory for compliance with the order.

For expungement of a convicted offender DNA sample, the CODIS Manager will follow the protocol in the CODIS Manual.

9.10 LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

The Laboratory Information Management System (LIMS) maintains the chain of custody and provides meaningful information and statistics on the type and number of requests received, on case turnaround time, and case work backlogs that will assist laboratory management in evaluating Division and laboratory objectives.

In addition, there are a series of reports designed to assist both users and management staff in the performance of their duties. Information and instructions may be found in either the LIMS Procedures Manual or in the on-line Help file of LIMS.

10 CASE MANAGEMENT

The CLD strives to complete the analysis of submitted evidence accurately and within the time constraints required by the submitting agency. The analytical process must not be open-ended. Supervisors will be responsible for monitoring the status of all cases in their section. The laboratory should inform the customer of any major delays in analyses. If there is not an expectation that evidence will be needed for examination/comparison within a reasonable time frame, the evidence should be sent back to the submitting agency until a mutually agreed upon time can be established for resubmission, if necessary. If for any reason the crime lab is not able to honor a request, the customer will be notified. Documentation of this communication must be entered in the case file.

10.1 CASE RECORDS AND DOCUMENTATION

10.1.1 Policy

Case Records (i.e., all administrative and examination documentation) will be identifiable, accessible to authorized personnel and properly stored to prevent damage or loss. Case documentation will contain sufficient information to facilitate identification of factors affecting measurement uncertainty and to enable the test to be repeated under conditions as close as possible to the original. Records will include the identity of personnel responsible for the sampling, performance of each test and reviewing and reporting of results.

10.2 PROCEDURE

10.2.1 Administrative Documentation

Administrative documentation must bear the laboratory case number and initials or signature in order to be placed back into a case file if it becomes separated. If signatures are present, initials are not required. It is the responsibility of the staff member adding the administrative documentation to the case file to ensure it is properly initialed or signed and has the correct lab number. Page numbers are not required for this documentation; however nothing in this section precludes the optional use of page numbering if desired. If the administrative documentation is a packet of material (such as an officer's report) that is securely stapled together, the case number and initials or signature only need to be on the first page.

Examples of administrative documentation include:

- Request for Laboratory Examination (RFLE)
- Cover letters, officer's reports, and other information relevant to the case
- Evidence transaction records including any submitting agency forms used in lieu of the RFLE for documenting the chain of custody
- LIMS printouts
- Court orders

10.2.2 Examination Documentation

Examination documentation must support the conclusions stated in the laboratory report. Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task (ISO 4.13.2.2). Nothing in the case notes and examination documentation may be erased, made illegible or obliterated. Documentation will be permanent in nature and recorded using ink unless the use of ink is made impractical by environmental conditions such as cold or rain. If notes are recorded in pencil, they must be duplicated in ink as soon as possible. Pencil is appropriate for diagramming or making tracings. Pages of notes that will be destroyed due to chemical or biological contamination can occur only after the pages have been photographed or otherwise reproduced for preservation, and the reproduced record is reviewed and complete prior to destruction of the original record.

Changes, additions, or any other form of alteration must be initialed by the person making the alteration. When mistakes occur in examination documentation, each mistake shall be crossed out and the correct value entered alongside. If an observation, data, or a test result is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record. If case notes or examination documentation are created electronically, the documentation will be considered completed and "stored" when the draft report is prepared and before the case file is technically reviewed. If changes to the electronic notes or documentation are required after being initially stored, the original will be "archived" in the electronic case file and the updated version renamed and saved.

Case notes and examination documentation must be marked with:

- Unique laboratory numbers
- Handwritten/digital initials or signature of the examiner
- Dates of examination
- Page numbers

The unique identifier for each case for which data is generated shall be appropriately recorded on the printout when data from multiple cases is recorded on a single printout.

The page numbering system:

- Must readily show if a page of documentation is missing
- Will show the individual page number on each page and the total number of pages on the first page
- Will have any double-sided page treated as a separate page and numbered separately

- Will be numeric, except for additions that occur after the document was originally numbered. These additions will be expressed by a letter (a, b, c upper or lower case) after the page number and the additions will be noted along with the total number of pages on the first page.

The start and end dates of testing must be documented in the case record to allow for traceability of materials used in analysis. The start date of testing is documented as the date case documentation begins and the end date is indicated by the draft complete milestone in LIMS. (For CODIS, the end date is the "Analysis Complete" date which is documented on the last page of the case file.)

Abbreviations are acceptable if they are readily comprehensible to a reviewer or if a key is available.

Case notes and examination documentation include but are not limited to the following:

- Descriptive information pertaining to the case and the evidence:
    - case numbers
    - evidence descriptions (item numbers, packaging, seals, quantity, size, physical appearance, condition, and adhering materials)
- Photographs, digital images, and diagrams
- Discrepancies between evidence listed on the request form and the actual evidence
- Examination procedures used and the parameters for those procedures
- Records of data; results of examinations; handwritten or machine-generated notes, forms, and observations; chromatograms, spectra, and other instrumental printouts; photographs, drawings, and other illustrations; identity and source of any standards or references used. When a test result or observation is rejected, the reason(s) should be recorded. Selection of a stronger or clearer test result or observation from replicate test results or observations is not a rejection of the other test results or observations.
- Notations showing the generation and disposition of new evidence items such as trace collections, substrate controls, etc.
- When analytical equipment or instrumentation is used, the procedure and/or any specific operating parameters and the instrument used must be noted in the case record. This will be addressed in the specific functional area technical manual. In a laboratory with only one instrument for a specific test or procedure, the instrument's identification is documented in the laboratory's equipment list. In laboratories or units that have multiple instruments of the same make/model, one must record the unique identifier of the instrument used in the case notes or on the hard copy instrument data.
- Where appropriate, diagrams and/or photographs should be used in addition to narratives, to record observations. Photocopies or printouts of digital

images may be suitable in some instances (i.e., thin layer chromatography, questioned documents, etc.)

- Observations, data and calculations must be recorded at the time they are made, and must be identified to the specific analysis or test
- Notes are intended to record observations made during examination. If it is necessary to rewrite notes to make them more legible, the original notes must be retained in the case file
- If a sampling plan is used, reference must be made to the sampling plan in the examination notes. Notes must include the date(s) sampling was performed, location of the sampling, clear indication of what evidence was sampled (item numbers), environmental conditions that may affect sampling
- Documentation to support conclusions shall be such that in the absence of the analyst, another competent analyst or supervisor could evaluate what was done and interpret the data

10.3 DIGITAL IMAGES IN CASEWORK DOCUMENTATION

This section covers digital imaging used for the purpose of documenting casework: it does not address digital images that are considered to be evidence, which is covered under the Evidence section of this manual. Image capture devices should be capable of rendering an accurate representation of the item of interest. Different applications will dictate different levels of resolution for both the image capture and final output. All equipment should be maintained according to the manufacturer's specifications.

Output devices should be capable of producing accurate representations of input images. The levels of resolution for printed or transmitted images will depend upon the application and need.

Original images will be stored and preserved in an unaltered state. This includes maintaining original digital images in their native file format. Duplicates or copies will be used for working images when image processing is required.

Preservation of original images using the following media is recommended:

- Write-once Compact Disk Recordable (CDR)
- Digital Versatile Disk Recordable (DVD-R)
- External hard drives
- Secure servers

If the images are preserved on a CDR or DVDR, the disk will be retained in the case file.

If the images are stored on an external hard drive or secure server, the file name and file path will be documented in the case file.

10.4 LABORATORY REPORTS

10.4.1 Policy

All casework results and conclusions will be documented in original written reports that are printed on departmental letterhead and signed by the scientist performing the work. Searches listed in the report (CODIS or IBIS) must be completed within 60 days of the release of the report. Scientists will ensure that the results of each test performed for the request will be reported accurately, clearly, unambiguously and objectively and will include all the information requested by the customer and any information necessary for interpretation of the test results.

10.4.2 Procedure

The laboratory report is written for the laboratory's customers as a response for a request(s) for service. These customers include law enforcement officers, attorneys (both prosecutors and defense attorneys), fellow scientists and other specified individuals involved in the case. The report communicates a description of the items received and tested, the results of the test, and conclusions that may contain opinions and interpretations.

Each laboratory report shall include at least the following information, unless the laboratory has valid, documented reasons for not doing so:

- A title, Crime Laboratory Report
- The name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory
- The Lab number unique to this report, on each page of the report
- Clear identification of the end of the report (typically by including the page number and total number of pages)
- The request number(s) associated with the Lab number for the work covered in the report
- The name and address of the submitting agency
- The name of the requesting customer
- A reference to the analytical methods used
- Description of the sealed state of the evidence as received by the examiner
- A description of, and condition of, the items analyzed and their unique identifiers
- Disposition of all evidence items received, created, recovered, retained or consumed by the analyst
- Reference to other items of evidence received but not examined (if applicable)
- Results of analyses including the units of measurement where appropriate
- Any deviations from the procedure and information on specific test conditions when necessary

- If a sampling plan is used, the report shall contain information about the sampling plan, including confidence levels and corresponding inference(s) regarding the population
- Where necessary for the interpretation of the test results, a statement on the estimated measurement uncertainty; information on uncertainty is needed in lab reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit stated by a regulatory body, a statute, case law, or other legal requirement
- If applicable, description of any appendices to the report
- Results of tests performed by subcontractors will be clearly identified in the report
- If applicable, initial database entries (e.g., CODIS, AFIS, NIBIN)
- Reporting of associations resulting from a database search
- If applicable, the extent of database (e.g., CODIS, AFIS, NIBIN) searches, unless otherwise communicated to customers in the Forensic Services Guide
- When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report (see discipline technical procedures for how to properly qualify the significance of associations)
- When comparative examinations result in the exclusion of an individual or object, the report shall clearly communicate the exclusion
- When no definitive conclusions can be reached, the test report shall clearly communicate the reason(s)
- A signature block including name and title of the person performing the analysis and the date the report is signed. The signature block for seized drug reports shall comply with all current applicable Washington State court rules, as currently found in CrRLJ 6.13(b). The analyst's email address may be included as part of the contact information at the analyst's discretion.

Any additional information pertaining to the case and the tests performed not specified above will be maintained in the case record as it is not possible to include all the case related information in the laboratory report.

The report should be as brief and clear as possible to facilitate understanding by the customer and adhere to the following format:

- Overview [optional]
- Results and Conclusions [May include evidence listing for some seized drug cases]
- Evidence [Optional for some seized drug cases – see above]
- Methods and Observations
- Remarks [Optional]

Crime Laboratory personnel who issue findings or conclusions, including writing test reports and providing testimony, based on examination records and/or reports generated by another FLSB forensic scientist(s), may do so only after the referenced report has gone through technical and administrative review. (Police reports or medical examiner/autopsy reports are not subject to Division administrative reviews but these reports should also be reviewed if used as reference documents.) All such findings or conclusions must be based on information contained within the referenced report(s), associated notes within the referenced case file, or further examination(s) by the author. The laboratory case file will contain a copy of the referenced report(s). Relevant pages or material that was referenced in the case file will be documented in the case file with the analyst's initials.

If analytical work has already been performed and the customer informs the laboratory that a report is not needed, a technically and administratively reviewed report will still be issued.

The CLD does not require a written laboratory report for the database entry of fired cartridge cases into IBIS/NIBIN. Refer to the Firearms and Toolmarks Technical Procedures Manual for additional details on crime lab reporting of IBIS/NIBIN entries.

10.4.3 Certifying Test Results

All completed laboratory reports will be signed on each page by the forensic scientist who completed the requested examinations. By signing the report, the scientists certify that they were the individuals who completed the testing as outlined in the report, that the report is a true and complete account of the testing performed, that the conclusions are supported by the testing, and that they are qualified, through training and experience, to perform the testing and make the conclusions as detailed in the report.

10.4.4 Reporting of Opinions and Interpretations

Within the disciplines of forensic science accredited by ANAB, it is possible to see at least four categories of laboratory reports:

1. Reports which contain only test results:
   For the purposes of this discussion and interpretation, a "test result" is generally one generated without human intervention to evaluate test data. No conclusion, opinion or interpretation is offered as to what the test means or may mean.

Example: A search of the hard drive failed to locate any occurrence of the phrase "unknown suspect."

2. Reports which contain test results enhanced with a conclusion, opinion or interpretation:

A test result enhanced with a conclusion, opinion or interpretation is one which provides the test result and also includes the analyst's or examiner's conclusions, opinion or interpretation as to what the test result means or may mean.

Example: The markings on the questioned bullet (Q1) were consistent with the markings on the bullet (K1) fired from the weapon (K2) submitted as Item 1. There is sufficient agreement to conclude that Q1 was fired from K2.

3. Reports which contain only a conclusion, opinion or interpretation:
   In some disciplines accredited by ANAB, test results are recorded in the technical records (case notes) but are not reported in the laboratory report. Only a conclusion, opinion or interpretation of the test result is provided in the test report.

Example 1: The latent print removed from the beer can (item 1) was identified as having been made by the same individual who made the left index finger of the known inked impression bearing the name John Doe (item 2).

Example 2: Item 2: White Powder – Identified as heroin

4. Reports which do not contain a test result, conclusion, opinion or interpretation:
   For a variety of reasons, a laboratory may generate a report to close out a submission that a customer no longer needs worked. A simple crime scene report may not contain any test results, conclusions, opinions or interpretations.

Example: At the request of submitting officer John Doe, all evidence is being returned with no analysis being conducted.

The basis upon which the opinions and interpretations have been made must be documented in the case notes. Opinions and interpretations will be clearly identified as such in laboratory reports, with one of the following options:

- A statement above the signature line which reads "This report may contain the analyst's opinion(s) and interpretation(s)" or "This report contains the conclusion, opinions, and interpretations of the analyst whose signature appears on the report"
- A heading for the section of the report that reads "Results and Conclusions"

10.4.5 Draft Reports

In preparing a laboratory report, the initial attempt may require modification before the analyst is satisfied that it accurately conveys the work done and the analyst's conclusions. The document may be considered a work in progress until the analyst feels that it is ready for technical review. When mistakes occur in draft reports, each mistake shall be crossed out, not erased, made illegible or deleted,

and the correct value entered alongside. All such alterations shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

Every effort will be made to prepare a draft report that holds up to technical and administrative scrutiny. The draft report should be clearly marked as a "Draft"; all pages of the draft report will bear the author's initials and date. The final draft report with the technical reviewer's sign-off initials or signature and date will be retained in the case file.

10.4.6 Releasing the Report

After the technical and administrative review of a report has been completed and documented, an original signed report will be released to the submitting agency. Copies of the report may be provided to a prosecuting attorney with jurisdiction and to other parties or by court order. If the report is sent initially by electronic means, the electronic transmission must be followed by a hardcopy original signed report. Upon distribution of the original report, the Distributed milestone in LIMS will be marked. A copy of the original signed report must be kept in the case file.

10.5 REVIEW OF REQUESTS

10.5.1 Policy

The WSP CLD will ensure that the customer's requirements, including methods to be used, are adequately defined, documented and understood; that the laboratory has the capability and resources to meet the requirements of the request and that the appropriate test is selected and capable of meeting the customers' request requirements. The review of the request will also cover any work that is subcontracted by the laboratory. The WSP CLD will have initial discretion over the selection of methods for analysis, the totality of the analysis and the items tested.

10.5.2 Procedure

A Request For Laboratory Examination (RFLE) form must generally accompany all evidence submissions. A request form may be submitted prior to the submission of the actual evidence, but all evidence received by the laboratory must have an associated request form.

Prior to the start of testing of evidence, CLD personnel will review the evidence and case information against the services requested on the RFLE to confirm that the CLD has the appropriate test methods, capability, and resources to perform the services requested.

The review will be documented by initialing and dating of the request by the supervisor or scientist, by creating documented case communication with the

investigator, completion of the request, or by other demonstrable evidence that the review took place within the first 60 days. All accepted requests will be assigned by supervisors or designee as soon as practical. The date that cases are assigned will be documented in LIMS.

Although timeliness is important, quality will not be sacrificed in order to meet a deadline. If meeting a deadline is likely to compromise quality, staff may consider options including transfer of the evidence to another laboratory. If options are not feasible, staff will consult with the submitting agency and/or the prosecuting attorney and advise them the work cannot be satisfactorily completed within the imposed timeframe. If a resolution cannot be reached, this will be communicated up the chain of command as appropriate.

Lab managers will work with the supervisors to ensure that good customer service is provided on all unassigned cases. A monthly report of requests older than 180 days will be generated by the supervisor and given to the lab manager. For cases approaching 365 days from date of submission, if there is no reasonable expectation the request will be worked in a timely fashion (e.g., 180 or more days from this review), the agency will be contacted by the supervisor or designee. The agency contact will be documented in the case file. If appropriate, the evidence should be returned and the request cancelled.

After the request has been reviewed, a scientist will inform the customer and notify their supervisor if the CLD is unable to fulfill the request for services and the reason. Any differences between the requested services and the services that the CLD can provide will be resolved before any work commences. Documentation of this contact, at a minimum, will be placed in the case info file tab in LIMS. Once the CLD has received and accepted the evidence (through submission on the RFLE), it is the CLD responsibility to determine the best analytical approach for the evidence. It is understood that the most effective use of resources may not allow all evidence items to be examined. For example, if multiple items are submitted in a single-suspect seized drug case, only a single item may be analyzed and the agency would not receive pre-notification beyond what is described in the Forensic Services Guide.

Any subsequent amendments or deviations from the initial agreed upon services will be documented at minimum in the case info file tab in LIMS. The customer and affected personnel will be notified.

10.6 REVIEW OF CASEWORK

10.6.1 Policy

Each laboratory will ensure that conclusions are reasonable and supported by the examination documentation and that established policies and procedures are being

followed. All laboratory reports and associated case documentation will be subject to technical and administrative reviews.

10.6.2 Analyst Review

Analysts will conduct a thorough review of their own work prior to technical review. This review is done after all analyses for that request are complete and the draft report has been printed where applicable. The analyst documents this review by dating and initialing or signing the draft report. (For the CODIS Laboratory, this documentation is the "Analysis Complete" date found on the last page of the case file). The analyst review is a complete review of the case file consisting of all the elements of the technical and administrative reviews. Producing quality casework is a normal job function of all scientists qualified to perform casework, and the quality of casework will be documented and evaluated by supervisors. The author of the case report has the primary responsibility to make sure that their draft report and case documentation are complete and of the highest quality.

The reporting analyst is the person responsible to ensure that the distributed report is an accurate representation of the case results. The analyst's reported conclusions must:

- be able to stand alone without the necessity of explanation by supporting verbal testimony
- be accurate, thorough, and clearly stated
- be supported by the data
- clearly distinguish fact and inference
- appropriately address the customer's questions

Analyst reviews will include, but are not limited to, the following:

- Examination of the draft report for proper spelling, punctuation, grammar, and for transcription errors
- Examination of the report for appropriate references to work done in the laboratory, including other lab reports, amended reports, laboratory item numbers, work referred to other analysts or other laboratories, evidence received but not examined, evidence disposition, and analysts' signature
- Comparison of the agency name, address, agency case number, agency item numbers, investigating officer, initial chain of custody or when received into the laboratory and suspect/victim information on the report to the information provided on the request form and in LIMS or casework database
- Verification that each page of the case file has the required identifying information including case number, page number, initials and date, and that corrections are documented with initials
- Verification that examination documentation is complete
- Verification that the case file is complete

10.6.3 Technical Review

- Technical review will be conducted on all cases before release of written and verbal/email reports. This is to ensure that the results, opinions, interpretations and conclusions stated in the draft report are properly qualified and supported by the case record. The technical review is also performed to ensure examination documentation is complete and accurate and that the final report will be free of omissions and errors. Technical review is a normal job function of all scientists qualified to perform that function, and will therefore be subject to documentation and evaluation by supervisors. While the final responsibility for the scientific findings in the report rests with the analyst, the technical reviewer is equally responsible for the quality of the report and both will be held accountable.
- Assignment of cases for technical review is the responsibility of section supervisors. Technical review is to be conducted by authorized individuals who have been competency tested in the testing being reviewed and who are currently performing casework or have completed proficiency tests in that category of testing within the last two years. An exception to this is in the technical review of DNA cases, where the technical reviewer must be current with their proficiency testing. Technical reviews shall not be conducted by the author or co-author(s) of the examination documentation or draft report under review.
- The technical review process should be undertaken as soon as practical after the case is completed. Supervisors will be responsible for monitoring the process.
- The technical reviewer will ensure:
    - Examinations conducted are appropriate to satisfy the request made by the customer
    - Conformance with test methods and applicable policies and procedures
    - If an analysis was not conducted, the reason is supported by established laboratory policy
    - Communications and phone notes are present if applicable
    - Examination documentation supports the conclusions stated in the draft report
    - Conclusions are reasonable and stated unambiguously, neither overstating the significance of the findings nor omitting any reasonable conclusion
    - All relevant case information is included
    - Descriptions of evidence and evidence packaging are complete
    - All procedures, data, results, and conclusions are documented
    - All calculations and data transfers are verified for accuracy

- Appropriate procedures were used and test parameters (for example, instrument operating parameters) were appropriate for the examination.
- Any deviations from established procedures are recorded in the case file, technically justified, authorized, and accepted by the customer.
- Appropriate standards and controls are used when necessary and documented
- All items listed on the lab request are accounted for in the draft report
- Generation and disposition of new evidence items such as trace collections, substrate controls, etc., is documented
- All strikeouts or insertions are noted with the examiner's initials. Overwrites must be struck-through, rewritten, and initialed. No obliterations should be present.
- All pages of examination documentation are labeled with the case number, dates, examiner's handwritten initials, and page number. The total number of pages of notes is documented on the first page.
- The draft report is clear, concise, and initialed and dated
- Opinions and interpretations are clearly identified as such, are accurate and properly qualified
- The answer sheet for proficiency tests has been fully completed and is free of errors
- Excessive errors or insufficient data to support the conclusion are brought to the attention of the supervisor
- Discipline-specific requirements for technical review are met.

An approved discipline specific technical review checklist will be used to facilitate the review process and be retained in the case record as administrative documentation. All changes made to technical records as a result of technical review shall be tracked. Tracking must indicate who made the change, when the change was made, and what was changed. Tracking can be accomplished in a variety of ways, including but not limited to saving draft reports, noting the changes on the technical review checklist and through document track change functions. The analyst must address all the observations and recommended corrections of the technical reviewer.

If, during the technical review process, there are significant concerns regarding technical or quality issues, such as those listed below, the case file must be turned over to the supervisor.

- The case notes and analytical documentation do not support the conclusions stated in the report

- The case notes and analytical documentation are not clear in content, intent, or purpose
- The case notes contain procedural errors
- The case notes, analytical documentation, or report exhibit numerous errors not appropriate for the complexity of the case
- The case notes contain inappropriate strikeouts, obliterations or overwrite or cut-and-paste errors
- Issues or discrepancies are not successfully resolved

The supervisor will evaluate the concerns and, if appropriate, notify the Laboratory Manager and the Standards and Accountability Manager. If the case involves DNA analysis, the DNA Technical Leader will also be notified (see also the section on Nonconforming Work and Corrective Actions). Substantive nonconformities or recurring nonconformities discovered during technical reviews are to be brought to the attention of the SAS Manager and Laboratory Accreditation Manager through the chain of command as soon as possible. The Corrective Action process will be followed.

Complex or difficult cases may require more time in order to do a thorough review. Supervisors are responsible for ensuring that cases are reviewed in a timely manner.

Errors discovered after the technical review process may be addressed by Corrective Actions and will involve both the originating scientist/author and the technical reviewer.

Technical Reviews will be documented with the reviewer's initials and date on each page of the draft copy of the report, and in LIMS. (For the CODIS Laboratory, the reviewer's initials and date are on the first page of the case file). The presence of the reviewer's initials indicates that the bench notes, data, spectra, photographs, and other documentation found in the case file clearly support the conclusions stated in the report.

If minor corrections are identified that need to be made to the draft report, the reviewer can clearly mark them on the draft report with their initials. If the reviewer determines that, with these changes, the case file meets all of the above requirements, the reviewer can initial each page of the draft report and document technical review complete in LIMS. In such instances, the analyst must make all the changes as indicated by the reviewer. If the analyst disagrees with the changes indicated on the initialed draft, the report cannot be released and the analyst will need to contact the technical reviewer and resolve the disagreement or follow the mediation procedures described below in section on Resolution of Technical Differences of Opinion.

10.6.4 Inter-lab Technical Review

In some labs in the CLD there are insufficient analysts to conduct technical reviews of all cases. It is therefore necessary to submit case files to other labs for review. In addition, it has been determined that a quality improvement can be obtained by submitting routine casework for review to scientists outside one's own laboratory. Therefore, the Quality Process Manager, working in conjunction with the functional area supervisors, will develop a schedule for inter-lab technical review.

All cases submitted for inter-lab technical review will be handled using the following guidelines:

- When submitting case files to other laboratories for inter-lab technical review, precautions must be taken to avoid the loss of case file documentation, particularly that which is difficult if not impossible to reproduce. Original case file documentation which cannot be reproduced (i.e. RFLE, case notes) will be retained by the submitting laboratory unless hand delivered and returned; otherwise only copies of this documentation will be sent out for review. Original case file documentation which can be easily reproduced (i.e. instrument data) may be sent out for review and does not need to be hand delivered or photocopied.
- For scheduled inter-lab reviews, rush cases will not be submitted unless both parties agree.
- Supervisors will be responsible for selecting cases for inter-lab technical review and will monitor the program.
- Reviewers will conduct technical reviews in a timely manner. Supervisors will be apprised of any delays.
- Documentation of the technical review will be by dated signature or initials on all pages of the final draft report or photocopy. If a photocopy, the photocopy will be retained in the case file.

10.6.5 Administrative Review

An administrative review will be conducted on the case file and final report prior to the release of laboratory reports, amended reports and proficiency test answer sheets. The administrative review is designed to ensure that:

- The report or answer sheets being released correctly and completely reflect the draft report, including any minor corrections indicated on the draft by the reviewers
- The report or answer sheets being released do not contain misspelled words or grammatical errors
- The evidence item numbers and case numbers are correct
- Case notes are initialed and dated
- Administrative documentation is identified with the case number and initials/signature

- A technical review has been completed and is documented on the draft report, technical review checklist or answer sheet
- Proficiency tests contain a copy of the answer sheet with case numbers, initials and documentation of technical review, to remain with the file; administrative review may also be documented on the answer sheets

Administrative reviews will be conducted by technical staff, supervisors or lab managers. The administrative reviewer does not have to be technically proficient in the functional area, but may not be the author of the report. The administrative review is documented in LIMS and may additionally be documented in the case file.

10.6.6 Verification of Physical Comparisons

A verification of physical comparisons is an examination of the evidence to verify another analyst's conclusions. Those cases where such a verification is required will be identified in the technical manuals for each forensic discipline.

Verifications are conducted by individuals having expertise gained through training and experience currently authorized to perform casework in the category of testing. Verifications will be a separate process from technical review, but may be conducted by the technical reviewer.

Verifications, including off-site verifications, will be documented in the case file and include the identity of the analyst performing the verification, when it was performed, and the results of the verification. The verifier will provide sufficient documentation to support his/her own independent observations and conclusions. Minimally, if the verifier draws the same conclusion as the primary analyst, documentation must include the verifying analyst's initials and date of examination. Where applicable, the scanned copy with the verifier's initials and date will be retained as the original. For situations where the verification does not agree with the original test result, the resolution of any discrepancy shall be recorded. Refer to the section on resolution of technical differences of opinion and nonconforming work, as applicable, for actions to resolve discrepancies.

All changes made to technical records, including the lab report, as a result of verification shall be tracked. Tracking must indicate who made the change, when the change was made, and what was changed. Tracking can be accomplished in a variety of ways, including but not limited to saving draft reports, noting the changes on the technical review checklist and through document track change functions.

10.7 TECHNICAL REVIEW IN SPECIAL SITUATIONS

10.7.1 Amended Reports

Contents of laboratory reports are occasionally modified by the generation of Amended Reports. The report must be titled "Amended Report," and a brief

explanation describing the need for the amendment must be the first sentence of the report. If the amended report revises a result or conclusion, the revised result or conclusion and the reason for the revision must be clearly stated in the amended report. The amended report will bear the case number, request number of the original report, and the corrected report language.

All amended reports must be documented in the Case Information field in LIMS. A copy of the original signed amended report shall be retained with the case record.

If the reason for the amended report is clerical in nature, the supervisor's review and approval is required. The supervisor will document their review and approval by initialing and dating the draft of the amended report.

If the reason for the amended report is due to a technical error or oversight, the amended report must be technically reviewed prior to release. The technical reviewer will document their review in the Case Information field in LIMS. The technical error or oversight must be documented and treated as a nonconformance (refer to the section on Nonconforming Work and Corrective Actions). Copies of all amended reports involving technical issues will be retained by the supervisor and may be audited by the Standards and Accountability Section.

10.7.2 Verbal/Email Reports

When necessary, a verbal/email report may be issued provided that the section supervisor or designee has approved that course of action and that the technical subject matter contained in the verbal/email report has been technically reviewed.

The issuing scientist must first draft a written version of the verbal/email report.

The verbal/email report will be submitted for technical review. The data supporting the verbal/email report will be initialed and dated by the technical reviewer. The technical reviewer will document the technical review by initialing and dating the written version of the verbal/email report. The supervisor and technical reviewer may be the same person provided that the supervisor is qualified in the relevant forensic discipline and is current with the required proficiency tests.

If fully approved through the processes described above, the scientist may release the verbal/email report. The verbal/email report will be documented by making a notation in the Case Information field in LIMS. The technical reviewer will also make a notation documenting their review in the same section in LIMS. The scientist will document on the written version of the verbal/email report the date, time, and name of the person to whom the verbal/email report was released. The written version of the verbal/email report must be maintained as a permanent part of the case file.

In some instances, not all of the casework will have been completed; however, the technical review must be appropriate for the level of completion of the analytical work and documented as such.

Results containing non-comparative information such as semen identification, indications of blood, presence of trace evidence, etc., may be released without technical review.

A verbal/email report must be followed by a formal written report once the casework has been completed.

The final technical reviewer must ensure that the formal written report is consistent with the verbal/email report issued previously. The technical reviewer will notify the supervisor of any inconsistencies or problems.

10.8 RESOLUTION OF TECHNICAL DIFFERENCES OF OPINION

Disagreements may sometimes arise between scientists during the technical review process. Every effort will be made to resolve these issues at the peer level. Technical reviewers may request changes in draft reports, further work to clarify issues, or further work to complete cases. If there are unresolved differences during the review, the following process will be used:

- The reviewer and the scientist will bring the issue to the attention of the supervisor who will act as a mediator
- If not resolved, the Technical Lead will review the issues and make a recommendation to the supervisor, scientist, technical reviewer, lab manager and the SAS Manager
- If no agreement is reached, the SAS Manager will then form an arbitration review committee
- The CLD Commander will be kept informed of the process
- The arbitration review committee members shall be scientists with independent casework experience in the subject matter, and at least one laboratory manager not associated with the issue
- Recommendations by the committee may include re-analysis, issuance of an administrative report by the review committee, or other suitable action. The decision of the review committee concerning the resolution of the case shall be binding
- NOTE: For cases involving DNA analysis, if mediation is not resolved at the supervisor level then a second mediation is to be done by the DNA Technical Leader or by a qualified DNA analyst approved by the DNA Technical Leader. If differences exist after this mediation, the DNA Technical Leader, in consultation with the SAS Manager, is empowered either to arbitrate the issue(s) or decide that a review committee should arbitrate. The

supervisor(s) and lab manager will be notified when mediation or arbitration is necessary, and the result of the process.

- The resolution will be recorded in the case file and concluded prior to the release and distribution of the laboratory report.

10.9 Focused Casework Review

When internal quality processes uncover significant errors in casework, or there is a complaint alleging misconduct or incompetence, the CLD Commander or FLSB Director may initiate a focused casework review. If a root cause analysis has been completed, the CLD Commander or FLSB Director will review the analysis and its recommendations and any other input from the SAS Manager as part of their deliberation as to the necessity of a focused casework review.

10.9.1 Review of Affected Cases

The focused casework review will be conducted by an appropriate scientist or panel of scientists chosen by the CLD Commander or FLSB Director. The reviewing scientist(s) will prepare a report summarizing the findings and forward the report to the SAS Manager who will review and discuss with the CLD Commander or FLSB Director.

10.9.2 Notifications

The SAS Manager or designee will notify ANAB within 30 days of the initiation of a focused casework review.

The FLSB Director will notify the Forensic Investigations Council within 30 days of the focused casework review.

Disclosures to prosecuting attorneys and the judiciary will be in accordance with WSP Regulation Manual section 6.01.065.

10.9.3 Removal from and reinstatement to Casework

The scientist who is under a focused casework review will be removed from casework by the CLD Commander until the matter is resolved as required by the section on Nonconforming Work and Corrective Actions. In addition to the fact finding, technical review, re-examination of evidence, or other action taken by laboratory management, amended laboratory reports may be issued in the affected cases to the submitting agency with copies to the prosecuting attorney's office. Reinstatement to casework will also be by the CLD Commander.

10.10 Courtroom Testimony

Testimony should be limited to the results of the staff member's direct work on the case in question, direct knowledge of the case events or an area of their expertise.

Most often requests for appearance will be through a subpoena. Every effort should be made to comply with requests for appearance regardless of whether a subpoena is received or not as this is the legal culmination of our laboratory analysis.

Subpoenas received that pose a scheduling conflict must be resolved. Resolution is generally done via conversations between the staff member and the person issuing the subpoena.

10.11 COURT TESTIMONY REVIEW

10.11.1 Policy

The testimony of each staff member, and former employees that provide testimony while under contract with the CLD, must be technically reviewed at least once every two calendar years. Documentation will be recorded for those who do not testify in the calendar year.

For scientists authorized in multiple disciplines, technical review of testimony shall be performed for all disciplines in which an analyst is authorized to conduct casework, and for which they testify, during a four year cycle.

Mock trials/moot courts are not a substitute for actual testimony for this requirement.

10.11.2 Procedure

10.11.2.1 Court Testimony Review Methods

Technical testimony review methods include:

- Direct observation of the testimony by a qualified individual;
- Review of a video recording of the testimony;
- Use of a video conferencing system to observe the testimony “live”.

Annual testimony review, whether or not a technical review, is recommended and can be accomplished by the above listed methods and:

- Review of an audio recording;
- Review of testimony transcripts;
  Solicitation by a laboratory manager or supervisor to one or more officers of the court for evaluation of the testimony

10.11.2.2 Requirements

Prior to going to court to testify it is the duty of the staff member to inform their supervisor. After testifying, each person is responsible for entering the time spent related to testimony into the Activities Section of LIMS, recording time including travel and preparation time.

10.11.2.3 Technical Reviewer Requirements

Technical review of testimonies is to be conducted by authorized individuals who have been competency tested in the testing being testified to, and who are currently performing casework, or have completed proficiency tests in that category of testing, within the last two years. The technical reviewer must be a Forensic Scientist 3 or higher.

10.11.2.4 Supervisor Requirements

If the testimony was directly observed, the testifying staff member will be given feedback through their supervisor and/or the reviewer on the positive aspects of the testimony as well as the areas that may need improvement. If a court testimony was not directly observed, the supervisor may consult with an officer of the court who was present for feedback on the testimony, except for technical reviews. A transcript of the testimony may be obtained for review. Information received in this manner will be shared with the staff member.

Time spent by the supervisor and/or testimony reviewer in monitoring the testimony will be entered into the Activities Section of LIMS for the lab number addressed by that testimony.

Testimony review will be documented on the court testimony evaluation form and placed in the individual's supervisory desk file. The supervisor and/or designee will discuss the assessment with the staff member; the staff member and supervisor/designee will sign and date the form. Any problems identified from the review of testimony will be addressed by the supervisor and documented in the supervisory desk file. (See section on Nonconforming Work and Corrective Actions)

NOTE: Copies of the court testimony evaluation form shall be retained for at least one cycle of accreditation (four years).

10.11.2.5 Laboratory Manager Requirements

Provided that testimony occurred, it is the responsibility of the Laboratory Managers to ensure that testimony of all staff members be technically reviewed and documented at least once every two years. Laboratory Managers will also maintain testimony review records for former CLD employees who provide testimony while under contract with CLD.

10.11.2.6 Evaluation Criteria

Evaluation criteria will include:

- Communication Skills
- Demeanor
- Objectivity
- Appearance
- Apparent preparation

- Technical knowledge
- Technical accuracy and clarity
- Other relevant comments

10.12 DISCLOSURE AND RELEASE OF INFORMATION

10.12.1 Policy

The CLD is required by law to disclose documentation and information when it is requested by the media, defense counsel, or other parties designated by the Public Records Act. These inquiries typically involve requests for forensic test results, test methods, and/or validation data.

All employees are responsible for maintaining confidentiality in all cases. It is the policy of the CLD to follow the WSP Public Disclosure procedures and to work with customers to honor requests.

10.12.2 Procedure

Discovery requests from the prosecutor will be referred to the appropriate scientist. If appropriate, the supervisor may notify the Laboratory Manager (e.g. for excessive requests, requests for staff DNA profiles). In most instances, a copy of the report and all requested case notes will be transmitted as soon as possible through the prosecuting attorney's office unless specifically ordered otherwise by the court or authorized by the prosecuting attorney.

If requested, these items can be provided via discovery request(s):

Note: The items listed below are not all-inclusive.

- Copy(ies) of the case file including electronic data CD
- Evidence Chain of Custody
- Proficiency test evaluation forms for up to two years
- Reporting scientist and technical reviewer CV's
- Copy of laboratory accreditation certificate and scope of testing
- Summary audit reports
- Current CLD manuals are available on the WSP external website. Archived versions of CLD manuals are on the FLSB Portal
- Copies of manufacturer product inserts
- Copies of internal validation (summaries only)

The section supervisor will be informed of all discovery or public disclosure requests.

Requests for information received from anyone other than the Prosecutor's Office will be coordinated and tracked through the Public Disclosure Tracking Coordinator (PDTC).

Public disclosure requests for information from cases where analysis has not been completed will also be forwarded to the investigating agency and Prosecutor's Office before responding to the request, in case there are legal objections to release of non-completed casework documentation.

For a subpoena duces tecum, the scientist/individual served will produce the required case records and forward to the PDTC. The PDTC will track the request, provide the requested records in response to the subpoena duces tecum, and notify the served individual when the records have been provided.

Requests for records kept outside the CLD (HRD, OPS, etc.) will be forwarded to the PDTC for response. Court orders for non-casework laboratory documentation will be forwarded to the PDTC.

Additional information regarding the release of DNA case files is found in the DNA Quality Assurance Manual under the "REPORTS AND THE RELEASE OF INFORMATION" section.

The case record will contain a record of the date the request was received, the date(s) the information was provided, and the records and information provided. If the request is excessive, the scientist involved should immediately notify their supervisor and mitigation will be sought. The assigned prosecuting attorney should be consulted first; the WSP Public Records Officer and the WSP representative in the Attorney General's Office (AGO) may also be valuable resources. Any contacts with the AGO will be routed through the chain of command to the CLD Commander or designee.

The prosecuting attorney and/or defense counsel may request a pre-trial conference with a scientist to discuss a particular case. Scientists should participate in trial preparation with attorneys, whether in face-to-face meetings or by teleconference.

10.12.3 Media Contacts

The CLD recognizes the need for a positive and open relationship with the media by maintaining a Public Information Officer (PIO). The CLD PIO is the QPM unless otherwise designated by the CLD Commander.

Media requests for information will be directed to the Division PIO who will notify the CLD Commander as appropriate. The Laboratory Managers or their designees will also be notified of such requests.

11 EVIDENCE MANAGEMENT

11.1 DIVISION POLICY

The CLD shall document a chain of custody on all evidence received from time of initial submission of evidence to time of evidence return to agencies. The chain of custody record shall document all internal transfers indicating each person taking possession of an item of evidence or the location of the evidence.

11.2 DEFINITIONS

11.2.1 Chain of Custody

Documentation demonstrating the receipt of, internal transfers, and the return of evidence to the submitting agency by the CLD laboratories.

11.2.2 Convenience Packaging

Convenience packaging is defined as a container used primarily to aid in the transport of the evidentiary items contained within. Convenience packaging will not have an evidence seal.

11.2.3 Evidence

A physical object, material or test item believed to have some investigative or forensic significance and defined as such by law enforcement personnel or forensic analysts.

- Items created from evidence that cannot be reproduced are generally considered evidence. When evidence, such as latent prints and impressions, can only be recorded or collected by digital imaging or photography and the impression itself is not recoverable, the digital image, photograph or negative of the image shall be treated as evidence.
- Digital images captured at crime scenes are considered evidence.
- Test fires submitted or created by personnel for comparison and/or IBIS entry are treated as evidence. Exceptions are made for test fires to be treated as “walk-ins” or IBIS drop box submissions. These are considered exemplars and not treated as evidence. Refer to the Firearms and Toolmarks Technical Procedures Manual.
- DNA samples (e.g. extracts produced in the lab), bloodstain cards (e.g. stains for DNA analysis made from reference samples) and microscope slides for DNA analysis are not considered to be evidence.
- Convicted offender DNA samples submitted to the CODIS Laboratory are not considered evidence.
- Items that are created from evidence by an analyst, and can be reproduced, are not considered evidence (i.e. photographic prints made from negatives, extracts where additional material is available to reproduce the extract, etc.).

Individual technical manuals will address specific issues for items created from evidence that can be reproduced and DNA analysis work products.

11.2.4 Evidence Packaging

Evidence packaging is defined as packaging that contains an evidence seal.

11.2.5 Evidence Seal

An evidence seal is a device or material that is used to close off or fasten an opening or connection in order to protect evidence from loss, cross contamination or deleterious change.

11.2.6 Exemplar Materials

Exemplar materials are representations illustrating the class and individual characteristics of a known object or source within a specific context. Exemplars are created in order to allow a comparison between the known object or source and a questioned item of evidence. Exemplars may or may not be considered to be evidence.

11.2.7 Final Disposition

Final Disposition is the last step in the chain of custody. This is most commonly the return of an item of evidence to the submitting agency. However, there must be documentation in the case record if the item is to be retained in the laboratory or if it is to be destroyed.

11.2.8 Laboratory Information Management System (LIMS)

LIMS documents the official chain of custody for evidence submitted to the laboratories. JusticeTrax LIMS-Plus is the CLD's Laboratory Information Management System which is used for tracking cases and evidence, and for generating analytical and statistical reports. LIMS is a secure electronic database and requires a user identification and password. A full description of LIMS is contained in the LIMS Technical Manual.

11.2.9 Limited Sample

A limited sample is one that is likely to be completely consumed during analysis.

11.2.10 Request for Laboratory Examination (RFLE)

The form (Form 3000-210-005) used by the submitting agency to formally request forensic services from the CLD.

11.2.11 Secondary Submission

Additional evidence submitted to the lab from an agency case that has already been assigned a laboratory case number.

11.2.12 Submission

Items received as evidence for a laboratory analysis on one or more RFLEs. (See LIMS Operations Manual.)

11.2.13 Transferred Case

Evidence in a case sent to another laboratory for analysis.

11.3 Handling and Preserving the Integrity of Evidence

The processes used to handle and examine evidence must be designed and carried out so that the evidence is protected from loss, cross contamination or deleterious change. The chain of custody must be maintained at all times and shall securely and accurately identify:

- the individual(s) or location(s) receiving or transferring the item(s);
- all evidence items transferred, received and handled by the laboratory, including those items not tested; and
- the chronological order of transfers, minimally including the date.

Laboratory staff will use a best practice approach when selecting examination order and techniques so that evidence is not compromised or unnecessarily consumed. All employees will share in the responsibility of ensuring that evidence is not lost, contaminated, or cross-transferred. Universal precautions to prevent contamination will be used when necessary.

Each laboratory will use a secure electronic chain of custody record through the use of the LIMS. This electronic record is the official chain of custody. However, the initial chain of custody is documented on the RFLE. Additional chain of custody documentation is allowed; however, all evidence transfers must be entered into LIMS. EXCEPTION: Crime Scene Response – CSRT documents evidence collection on the CSR Evidence Inventory Log (Form CSR-EIL-11003) for release to the investigating agency at the crime scene. This evidence transfer will be documented on the form by both the Crime Scene Responder and a representative from the investigating agency.

11.4 Evidence Marking and Sealing

(See also the Forensic Services Guide.)

Evidence is authenticated by marking it with a unique case number and a unique item number. These identifiers must be on the evidence packaging or on the evidence item itself if the item is unpackaged.

Evidence can be protected from loss, cross contamination or deleterious change by sealing the evidence in a container using tamper-indicating tape or similar device. If the evidence needs to be sealed in a container in order to protect it, all of the openings in the container must be sealed.

Staples are not considered tamper proof and do not constitute a proper seal. Evidence seals, including heat seals and pressure sensitive seals, must bear the initials of the person sealing the evidence. The initials must extend across the evidence seal onto the packaging.

It is not always practical or necessary to seal evidence in a container in order to protect it from loss, cross contamination or deleterious change. Large items such as furniture, doors and windows, and automotive components cannot be containerized and sealed in a practical manner. In these situations, the area of the item that has forensic importance should be covered so that the area is protected. The covering should be clearly marked indicating that this is the area of interest.

As a general rule, evidence that is received in a sealed condition should remain sealed except during analysis. If a sealed item needs to be opened prior to analysis (safety check, retrieve an RFLE, etc.), it should be resealed before storage in the evidence vault. This will help lessen confusion and prevent violating any evidence policies of the submitting agencies.

11.4.1 High Value Items

The marking of a valuable (high monetary value) evidence item should be done such that the marking does not deface or otherwise devalue the item.

Currency will be recorded and witnessed in the case notes with the denomination and count of the currency along with the total face value. The witness will sign and date the case notes. The last 4 digits of cards used for purchasing/banking (i.e. credit, debit, or EBT cards) are also recorded, but need not be witnessed.

11.5 EVIDENCE DESTRUCTION

Evidence is the property of the submitting agency and laboratory staff will not destroy items of evidence. Laboratory staff may destroy non-evidence proficiency test samples that are no longer needed as discussed in the section on Proficiency Test Samples. It may be necessary for evidence to be entirely consumed in an analysis (see Limited Samples below).

11.6 EVIDENCE RESPONSIBILITIES

Property & Evidence Custodians (PEC) have primary responsibility for the receipt, storage, and release of evidence. They are also primarily responsible for transfers of evidence between laboratories and in and out of the evidence vault. These

responsibilities include ensuring that the chain of custody is maintained on all evidence in their control and that all evidence is properly sealed.

Analytical staff is responsible for the security of evidence in their possession. This includes ensuring that the chain of custody is maintained and that evidence is properly sealed and documented for return to the submitting agency.

Evidence audits will be conducted in accordance with the WSP Regulation Manual and the Audit section of this manual.

Laboratory personnel will not routinely transport evidence to court. Transporting evidence between labs can be authorized by the lab supervisor or manager.

11.7 EVIDENCE RECEIPT

The RFLE is the source document for user agencies to submit evidence and request laboratory examinations. The RFLE must accompany all evidence submissions. This form contains the information initially entered into the Division's LIMS such as the name of the submitting agency, agency case number, suspect and victim names, requesting official, detailed list of evidence submitted, examinations requested, and chain of custody. When the casework is completed, the RFLE becomes a permanent part of the case file.

Evidence submission should be done by hand delivery or by means of a secure transport system. Evidence is routinely received and/or released by the laboratory via secure transport carriers. A secure transport carrier is a company such as United Parcel Service, Federal Express or the United States Postal Service.

Received evidence must conform to the preservation and integrity principles outlined in this manual. Recommended packaging protocols can be found in the Forensic Services Guide.

The CLD does not accept syringes, hypodermic needles, razor or scalpel blades, or any types of sharps evidence without management approval, as they may pose significant risk to laboratory personnel. This does not apply to knives or other sharps reportedly used in violent crimes. The crime laboratory will not accept any case that includes a needle alone or a syringe with the needle detached.

When cases are received with specific suspected contaminants suggested by the agency, such as certain poisons, supervisors or laboratory managers will have the authority and flexibility to accept such cases if Crime Lab personnel have authorization for safely handling the evidence and for conducting such analyses with accepted methods. Agencies should have prior approval from the local Crime Laboratory prior to submitting such items. It may be necessary to refer the agency to another laboratory more fully capable of handling these analyses.

Submitted firearms will be checked to see if they are unloaded and are safe to handle. The safety check will be performed by a firearms examiner or a person trained to perform this procedure. If a firearms examiner or other properly trained person is not available, the firearm must be placed in a designated area of the evidence vault until it can be checked. Once the firearm is checked and determined to be safe to handle, a notation to that effect will be made on the RFLE and on the packaging.

If agencies test fire their guns and submit just the test fires for IBIS entry, these are submitted/treated as evidence and returned to the agency, unless submitted as a "walk-in" or via the IBIS drop box. Refer to the Firearms and Toolmarks Technical Procedures Manual. Test fires created in the laboratory are treated as evidence, appropriately packaged, and returned to the agency either packaged with the original evidence or as a separate item. The new item will be documented appropriately in the case record.

If shipped evidence is received with evidence packaging lacking proper initials across the evidence seal, laboratory staff will initial the seal, add their own seal with their initials, or apply additional tape along with their initials in order to create a proper evidence seal. This will be documented in LIMS.

If shipped evidence is received unsealed and the evidence is such that it requires sealing in order to protect it from loss or deleterious change, the following options are available:

- The evidence may be returned to the submitting agency at the discretion of the Laboratory Manager.
- Laboratory staff may inventory and seal the evidence. The submitting agency will be notified and the condition of the packaging will be documented in LIMS. Documentation of notification will be in the LIMS case synopsis/notes field under the "Case Info" tab including the initials of the person recording the information and the date.

Packages and envelopes with evidence received by secure transport, and all convenience packages containing multiple evidence items, will be opened in order to verify the contents are consistent with the RFLE and so that the evidence can be properly documented, labeled, correctly stored, and entered into LIMS.

If the evidence received does not conform to the description provided on the RFLE, this will be documented on the RFLE and in LIMS. The submitting agency will be notified and the discrepancy resolved prior to analytical work commencing on an evidence item when the discrepancy involves evidence listed on the RFLE not being present or any difference that calls into question the chain of custody. Supervisors will determine if contact with the agency is appropriate.

When there is doubt as to the suitability of an item for testing, or the test required is not specified in sufficient detail, the laboratory shall consult the submitting agency for further instructions before proceeding and shall document the discussion. (See the Chapter on Review of Requests)

When receiving evidence, laboratory staff will:

- Leave original seals intact when possible.
- Locate the RFLE.
- If hand delivered, ensure that the "Submitted by:" block at the bottom of the RFLE contains a signature.
- Some agencies routinely submit evidence using their own chain of custody form. The agency form may be substituted for the chain of custody blocks on the RFLE provided the form is properly filled out and contains appropriate signatures.
- If secure transport (UPS, Certified Mail etc.) is used, document the courier and the tracking number in the appropriate block on the RFLE and in LIMS. If there is no signature in the "Submitted by:" block, LIMS shall have, as an option, an "Agency" in lieu of a named agency representative as the submitter.
- When evidence is received via secure transport carrier, the person that opens and inventories the package must sign the RFLE in the "Received by:" block at the bottom of the form and will be included in the LIMS chain of custody using a secure transaction as the person receiving the package from the carrier. The date and time entered in LIMS will be when they take possession of the package.
- A staff member that receives a package delivery, but does not open or inventory the package, need not sign the RFLE, but will be included in the LIMS chain of custody using a non-secure transaction. Documentation of the package receipt, and storage if applicable, will be made in the notes field of the evidence tab in LIMS and if appropriate, written documentation may be included in the case file. The secure chain of custody will begin when the person that opens and inventories the package takes possession of it.
- A laboratory number will be assigned to the case and will be entered into LIMS. All items received will be documented in LIMS. All evidence items will be marked with the laboratory number by affixing a bar code label. (See LIMS Manual).
- Secure the evidence in the laboratory evidence vault or alternate evidence storage facility.
- Document any discrepancies on the RFLE and in LIMS.
- Enter the evidence receipt into LIMS by:
    - Entering the agency name, agency case number, offense, Uniform Crime Reporting (UCR) code, and the offense date (if available)

  - Entering the suspect(s) and/or victim(s) name(s)
  - Entering each evidence submission and its chain of custody
  - Creating a lab request and linking it to the specific evidence item by "relating" the request
- A separate "request" bar code will be printed and affixed to the RFLE.

11.8 STANDARD EVIDENCE ABBREVIATIONS

Below is the approved list of abbreviations for describing the evidence received by the laboratory:

SE	Sealed envelope
SPB	Sealed plastic bag
SPPB	Sealed paper bag
SPKG	Sealed package
SBOX	Sealed box
SSTYRO	Sealed Styrofoam box
SCAN	Sealed can

It is not mandatory to use abbreviations; if not using abbreviations, write out fully the description of the evidence received. If using abbreviations, use the standard list.

If the item received is not described in the abbreviation list, write out the description fully.

If the evidence packaging is glue-sealed, gum-sealed, self-sealed or heat-sealed, the type of seal may be described in LIMS but it is not required. It is only required to indicate whether or not the item is in an appropriate sealed condition (i.e. sealed) as defined in the Forensic Services Guide. The seal description may also be combined with the approved abbreviations. For example, one SE (glue-sealed) or one SPB (heat-sealed).

To better describe a received item, additional information may either *be* combined with the approved abbreviations or written out fully. For example, one SBOX (rape kit) or one sealed hard plastic container.

11.9 EVIDENCE ITEMS PRODUCED DURING CASEWORK

Any substance permanently removed, extracted, or otherwise physically separated from a submitted item of evidence for any reason may be itself considered evidence. Individual technical manuals will address specific issues in this regard.

Any such substance must be collected in an appropriate container and handled in a manner that protects it from loss or deleterious change. If this substance represents a new item, then it must be accounted for by proper marking, sealing, and documentation in the case notes, laboratory report, RFLE and LIMS. All new items will be returned to the submitting agency with all of the original items upon completion of examination.

11.9.1 Crime Scene Evidence

Evidence collected by CLD crime scene responders will be fully documented and identified, and packaged as to protect it from loss, cross transfer, contamination and/or deleterious change. All evidence will be turned over to the agency with jurisdiction over the case. An exception will be photographs taken at the scene, which will be submitted to the agency as soon as possible.

11.9.2 Evidence Transfers

The location of all items of evidence while in the custody of the CLD will be documented in LIMS. EXCEPTION: Crime Scene Response – Crime Scene evidence collected at the scene is released directly to the investigating agency before subsequent submission to the Crime Lab for analysis.

Documentation of evidence in and out of the evidence vault and of the transfer of evidence items from one scientist to another must be recorded in LIMS. Secure transactions are mandatory whenever a laboratory staff member is involved in the evidence transaction, except as noted above for staff receiving but not inventorying evidence. Any exceptions to this policy must be approved by local laboratory management and documented in the notes field of the LIMS evidence tab. A transaction is considered “Secure” when a lab staff bar code is scanned and the lab staff member enters his/her PIN. “Via” is not a required field for secured transactions. Evidence transfers may also be recorded in the case notes.

Laboratories receiving transfers from other laboratories will follow the standard evidence intake procedures.

11.10 TOTAL TRANSFER

A **total** transfer between laboratories occurs when one laboratory has transferred all evidence items on an RFLE to another for examination. The original RFLE documents the chain of custody from the submitting agency and accompanies the evidence being transferred.

The transferring laboratory will:

- Assign a case number to the request;
- Appropriately document on the original RFLE what is being transferred;
- Retain a photocopy of the RFLE;
- Ship the original RFLE and the evidence to the receiving laboratory;
- Document the chain of custody transaction as detailed in the LIMS Manual (see LIMS Manual 20.05 and 21.0).

The receiving laboratory will:

- Document the chain of custody as the receiving laboratory as detailed in the LIMS Manual (LIMS Manual 20.04 and 21.0)

11.11 PARTIAL TRANSFER

A **partial** transfer occurs when only a portion of the evidence on an RFLE is transferred between laboratories.

The transferring laboratory will:

- Generate a new RFLE that retains the original laboratory case number and lists those items being transferred; retain a copy of the new RFLE;
- Ship the new RFLE and the evidence to the receiving laboratory, and include a photocopy of the original agency RFLE (which will document the chain of custody from the original submitting agency);
- Document the chain of custody transaction as detailed in the LIMS Manual (see LIMS Manual 20.05 and 21.0).

The receiving laboratory will:

- Document the chain of custody as the receiving laboratory as detailed in the LIMS Manual (LIMS Manual 20.04 and 21.0)
- Retain the original laboratory case number will be retained.

For transfers of evidence where the chain of custody is documented on an agency form, rather than an RFLE:

- The transferring lab will provide the receiving lab with:
    - Either the original agency chain of custody form for total transfers, or for partial transfers, a copy of the agency form;
    - The original RFLE for total transfers, or for partial transfers, a filled out new RFLE.
- The evidence will be returned to the originating lab ONLY in cases where the agency form was used in lieu of the RFLE chain of custody blocks. The originating lab will return the evidence to the agency using the agency form.

- Only the lab(s) receiving the evidence from the agency and releasing the evidence back to the agency signs the agency form. The RFLE will be used in all other situations.
- The agency will be provided a copy of the RFLE to show chain of custody from one lab to another.
- A copy of the agency form will be retained in the case file in instances where it was used in lieu of the RFLE.

11.12 LIMITED SAMPLE

If during the course of analysis a sample which cannot be reproduced is determined to be limited, the scientist must notify either the case detective/investigator or the prosecuting attorney, whichever is most appropriate, of the need to consume the entire sample. A representative of the law enforcement agency or the prosecuting attorney must provide written approval before the analysis may proceed. The written approval shall become a permanent part of the case file, and may be in the form of a note, memo, letter or e-mail.

11.13 EXEMPLAR MATERIALS

Exemplars may or may not be considered evidence. Please see the definition of evidence at the beginning of this chapter. Exemplars may be sent to the submitting agency along with the case evidence upon completion of examination.

These materials may include but are not limited to:

- Test prints from footwear or tires
- Test marks from tools
- Fingerprint exemplars
- Handwriting exemplars
- IBIS test fires

If considered evidence, these items will be given an evidence item number and entered into LIMS. These items will be sent to the submitting agency along with the case evidence upon completion of examination.

If the exemplars are not considered as evidence, these materials may be retained in the case file or in the laboratory (see the relevant Technical Manual). Copies of exemplar materials that are used as a mechanism to document the examination performed should be kept by the laboratory.

11.14 PROFICIENCY TEST SAMPLES

Proficiency test samples will be handled in the same manner as case evidence until the Quality Process Manager determines that all proficiency test requirements have

been satisfied or the samples are no longer needed for that purpose. See the section on Proficiency Testing.

11.15 EVIDENCE STORAGE

Evidence will be stored in the laboratory evidence vault or in an alternate evidence storage location within the laboratory. Alternate storage locations include evidence refrigerators/freezers, individual evidence lockers, or unit evidence storage areas. These facilities must be locked and secured during off-duty hours.

Evidence items are to be resealed as soon as practicable after the requested testing is completed. Evidence in the process of examination may be left unattended for short periods of time but must be in a secure laboratory area and protected from contamination or loss. Examples of short periods of time may include, but are not limited to, rest breaks, meal periods, phone calls and short conferences. If evidence examinations cannot be completed in a day, the evidence may be returned to the vault in an un-sealed condition, on a cart, for example, or one of the alternate storage locations listed above, provided the evidence is protected from loss or contamination and is clearly identifiable as evidence. Alternately, evidence may be left on the bench or examination table un-sealed, again as long as it is protected and identified as evidence. Seized drug evidence may not be left in the open but must be placed in locked storage. Under certain circumstances it may be necessary to leave evidence unsealed, pending further work, such as latent fingerprint cards held for future comparisons. In these situations, it will be permissible to leave the evidence unsealed as long as it is being stored in a protected and secure location, with a limit of one year. Beyond a year the evidence must be sealed.

Evidence that falls under the following categories may be kept in open laboratory examination areas if marked as evidence and protected from deleterious change:

- Evidence too large for the vault or alternate storage area;
- Evidence that requires special handling because of chemical or biological hazards, possible cross-contamination with other evidence, or to maintain evidentiary value (such as drying an item to be examined for DNA).

Specific types of evidence will be stored in accordance with requirements in the Forensic Services Guide.

Convicted offender DNA samples submitted to the CODIS Laboratory are not considered evidence and are retained in the laboratory indefinitely.

11.16 EVIDENCE RETURN

All submitted evidence including items generated during casework shall be returned to the submitting agency upon the completion of examination.

Evidence will be released only to the submitting agency or approved subcontracting laboratories. An exception is possible when there is a valid court order requiring the release of the evidence to a party other than the submitting agency, or the submitting agency directs the laboratory in writing. A copy of the court order or written request will be maintained in the case file.

Returned evidence must be properly documented on the RFLE (or on the agency chain of custody form if used) and in LIMS.

Evidence items returned or transferred by secure transport carrier require confirmation receipts which will be retained in the case file. If delivery confirmation is not confirmed within ten days of shipping, the lab manager will be notified. The lab manager will ensure that affected parties are informed as appropriate.

11.17 CANCELLED REQUESTS

Employees may cancel a request and return the evidence to the submitting agency at any time when the circumstances of the case dictate it. These circumstances may include, but are not limited to, lack of probative value of the evidence; insufficient information accompanying the evidence to perform the request; lack of response by the agency, prosecutor, or other submitter.

Note: If any analysis has been performed, a lab report is required regardless of the agency or prosecutor canceling the request.

Cancellation of requests, other than for administrative corrections of data entry, will be communicated to the customer, and that communication documented in the "Case Info" tab synopsis/notes field in LIMS.

11.18 HAZARDOUS MATERIAL

Unidentified material is not considered hazardous until it has been determined to be so by analysis. In order to comply with Federal Department of Transportation regulations regarding the shipping of hazardous materials, it is recommended that the laboratory follows the requirements of the small quantity exception rule (See Code of Federal Regulations 49 CFR 173.4) if possible. If not possible, agencies which have submitted evidence to the CLD that has been determined to be hazardous shall be asked to retrieve the evidence from the laboratory in person.

11.19 EVIDENCE AUDITS

Evidence audits shall occur as described in the Property Inventory/Audit section of the WSP Regulation Manual (21.00.020) and WSP Property and Evidence Custodian Manual.

All evidence audit reports and the inventory sheets from which the audit is conducted will be retained and centrally located in each laboratory through at least one cycle of accreditation (four years). If the audit requires the inventory of evidence in the possession of a scientist or other personnel who are not present, this will be conducted with a witness who will initial and date the portion of the inventory sheet that they witnessed. All inventory sheets will be signed and dated by whoever participated in the audit. These audit reports will be subject to inspection during the annual Standards and Accountability Sections audit.

12 NONCONFORMING WORK AND CORRECTIVE ACTIONS

12.1 POLICY

In the event that any laboratory member becomes aware of a nonconformity with any aspect of testing, work, or the results of this work (e.g., in analysis, proficiency tests, reports, testimony, or care and preservation of evidence), correction shall be taken immediately including any decision about the acceptability of the nonconforming work. When a nonconformity has been identified, an evaluation of the significance of the nonconforming work will be made. Where the evaluation indicates that corrective action is needed, the corrective action procedures shall be promptly followed.

Training for all employees on the corrective action process will occur within one year of employment. In order to enhance the quality and effectiveness of root cause analysis and corrective actions, training will include root cause analysis principles and processes and its acceptance within the laboratory environment as part of a just culture.

12.2 PROCEDURE

The Corrective Action procedure is a step-wise process as outlined below. The process is entered and tracked by entering into the Remedy Nonconformance Tracking Program (RNTP).

12.2.1 Identification

While not an exhaustive list, identification of nonconformities may occur through any of the following:

- internal or external inquiries or complaints
- quality control
- instrument calibration
- staff observations
- supervisor observations
- technical and administrative review of reports and case files
- indications of inadequate technical review
- calibration certification checking
- management reviews
- internal or external audits

12.2.2 Notification

When a potential nonconformity has been identified, the Standards and Accountability Section will be notified. Staff working in the DNA functional area or CODIS will use the appropriate Quality Variance (QV) RNTP entry, which will be submitted to the DNA Technical Leader with a copy to the Lab Manager. All others

will use the Notification of Nonconformance RNTP entry, which will be submitted to the Laboratory Accreditation Manager with a copy to the Lab Manager. A nonconformity as described in an internal or external audit report, a letter of inquiry from the ANAB/ASCLD/LAB Proficiency Review Committee, or a Court Testimony Performance Evaluation may also be acceptable forms of notification sufficient to initiate the corrective action process. Such notifications are entered into the RNTP, similar to QVs and nonconformities.

The notification may be documented and submitted using the RNTP by any staff member and is routed through their supervisor. A supervisor, Lab Manager, DNA Technical Leader, or SAS Manager can decide to propose a corrective action plan with the notification.

When a DNA analyst identifies DNA contamination by an employee outside of the DNA section the following notification process shall be followed:

- The DNA analyst shall inform their supervisor and Lab Manager of the observed contamination. The DNA analyst will complete QV RNTP entry. If the contamination is outside of the CLD, the analyst and supervisor will discuss the best approach for notification.
- The DNA analyst, and/or their supervisor, will consult with appropriate individuals (including, but not limited to, the contaminating employee and their supervisor) to determine the root cause of the contamination and possible preventive measures. The QV RNTP will be updated and completed by the DNA analyst, contaminating employee, or an appropriate supervisor (as determined by the Lab Manager) in a timely manner.
- The contaminating employee, their supervisor, the DNA analyst and the supervisor of the DNA analyst will acknowledge the QV using the RNTP, which will be updated as applicable.
- The DNA Technical Leader and the Laboratory Manager are notified through the RNTP as applicable.
- The DNA TL will review the QV entry, and if complete and accurate, will approve the QV in RNTP. The QV can be rejected if sufficient information is needed.
- Substantive noncompliance requires disclosure to ANAB within thirty days of determining that non-compliance has occurred. If the nonconformance has been determined to be substantive, the Laboratory Accreditation Manager will provide written notification to all involved parties and assign an individual to prepare the Root Cause Analysis and Corrective Action Plan. The thirty day clock will begin from the date of that notification. In consultation with all involved parties, the disclosure report will be prepared and submitted by the Laboratory Accreditation Manager.
- The Laboratory Accreditation Manager or, if DNA related, the DNA Technical Leader, may state in the RNTP, that follow-up is unnecessary if it is thought that the follow-up does not serve a useful purpose.

12.2.3 Root Cause Analysis

The corrective action shall start with an investigation to determine the root cause(s) of the problem. This is a process of fact finding used to evaluate all aspects of the incident, including the policy or procedure involved, to identify the basis of the nonconformity. This process is a tool designed to help identify what, how, and why an event occurred, or the underlying factors leading up to a casework error or nonconformity. There may be more than one cause for a nonconformity. Whenever a discrepancy or nonconformity occurs in casework or CODIS lab work, the cause(s) should be determined if possible. The Laboratory Accreditation Manager may assign members of the CLD other than the supervisor to conduct the root cause analysis investigation.

The investigation may include an evaluation of procedures, staff skills and training, consumable supplies, equipment and instruments, calibration status, customer requests and requirements, samples, reagents, controls, and other items as deemed necessary during the investigation. The investigator shall consult with all necessary personnel, including with the staff member involved, to determine the basis of the nonconformity as completely as possible.

Nonconforming work may be a systemic error rather than an employee error, or a combination of both. The root cause analysis may provide a platform for process improvement, and may help guide value-additive changes in policy and procedure.

Refer to Appendix 1 for root cause analysis guidelines and procedures.

12.2.4 Evaluation of the Significance of Nonconforming Work

The level of significance of the nonconformity will determine the appropriate corrective action. Nonconformities occur in a continuum of significance and severity. Because of this, they must be evaluated for their significance and a decision made regarding the appropriate corrective action for the nonconforming work. This evaluation is the responsibility of the Standards and Accountability Section: the DNA Technical Leader for DNA related incidents of nonconformance, and the Laboratory Accreditation Manager for all others.

The evaluation of the significance level of the nonconforming work must consider (see table below):

- The severity of the nonconformance
- The possibilities and implications of the nonconforming work recurring
- If there is/was laboratory compliance with its own policies and procedures
- The suitability of those laboratory policies and procedures

Nonconformance Evaluation Matrix				
Impact	**High**	**Corrective Action**	**Corrective Action**	**Corrective Action**
	Medium	Correction? Corrective Action?	Correction? Corrective Action?	Correction? Corrective Action?
	Low	Correction	Correction	Correction? Corrective Action?
		Low	Medium	**High**
	Frequency of Occurrence			

For instances where the nonconforming work is determined to be nonsubstantive, the correction or immediate action taken, as reported in the RNTP entry, may be sufficient, and no (or limited) further action would be necessary. However, the supervisor, Lab Manager, Laboratory Accreditation Manager or DNA Technical Leader (for DNA related incidents of nonsubstantive nonconforming work) may decide to implement a corrective action plan.

In instances where the Standards and Accountability Section determines the nonconforming work is substantive, the corrective action process, described below, will be implemented. Substantive nonconformities would result in a finding of nonconformance by an accreditation assessor and may result in immediate removal of the laboratory member from casework or relevant duty/responsibility by the appointing authority. If the nonconformity is determined to be related to a functional area wide, laboratory wide, or system wide deficiency, the Quality Assurance Manager and CLD Commander will ensure casework is discontinued as appropriate until the nonconformity is addressed and resolved. Where necessary, the customer(s) will be notified and work recalled.

If a Corrective Action is required, the Laboratory Accreditation Manager will assign a person to prepare the Corrective Action Plan. The DNA Technical Leader can designate the person to prepare the Corrective Action Plan if the nonconformance is in DNA.

12.2.5 Corrective Action Plan and Implementation

The individual preparing the Corrective Action Plan will, in consultation with the functional area's Technical Leads, supervisor, Management Liaison and/or DNA Technical Leader, identify potential corrective and preventive actions. They must select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. For the DNA functional area and CODIS, the DNA Technical Leader must approve all corrective action plans before they are implemented. The Laboratory Accreditation Manager must approve all others. Once the corrective action plan has been approved, as designated in RNTP, the CAP will be implemented.

Difficulties with an employee's individual work performance will normally be addressed by the employee's supervisor with assistance and input from other appropriate individuals if necessary. The actions taken to correct the problem should be focused on the professional development of the employee, which normally includes remedial training and other assistance designed to help the employee overcome the problem.

12.2.6 Timeline

A timeline for completion will be included in the CAP. If the planned actions call for interim reviews prior to completion, these shall be scheduled and included in the timeline. The approved CAP should indicate who will prepare the final corrective action report (most often the author of the plan). The Laboratory Accreditation Manager, Laboratory Managers and Supervisors will ensure that corrective actions are implemented and completed within an appropriate timeline.

12.2.7 Corrective Action Plan Completion

Corrective Action Reports (CARs) are prepared after completion of the CAP and document the results of the CAP. The report will document any required changes from the corrective action and should include any further needed actions or recommendations. In lieu of an IOC, the information may be entered into the RNTP. All CARs require approval by the Laboratory Accreditation Manager, and if concerning DNA, require the DNA Technical Leader's approval. Courtesy notifications will be given to the CLD Commander and all involved parties. Internal and external DNA QAS audits are reported to NDIS by the CODIS Manager on the Lab Audit Certification form. Electronic copies of all external DNA QAS audits and associated remediation are sent to NDIS.

12.2.8 Follow-Up

In order to ensure continued compliance and that the corrective actions have been effective, monitoring of the employee's performance, laboratory performance, or system performance will be conducted by the employee's supervisor, or the individual responsible for carrying out the corrective action plan.

The Laboratory Accreditation Manager will oversee that appropriate follow-up actions are taken and evaluate the effectiveness of the corrective action plan. This may involve review of casework and audits of the area of activity or section or laboratory.

Internal auditors will review corrective actions taken during the Annual Internal Quality Audit, and will look for reoccurrences of problems or documentation demonstrating that there has been no reoccurrence. (See ISO 17025:2005 clause 4.11.4.)

12.2.9 Reporting Requirements and Responsibilities

ANAB requires a summary of nonconforming work events, the actions taken, and summary of any other substantive corrective actions completed, or in process, since the last on-site visit included in each laboratory's annual provision of conformance documents. Each lab manager, with the assistance of the Standards and Accountability Section as needed, will prepare these summaries as part of the laboratory's required reporting to ANAB.

Records of Corrective Actions will be retained for at least one accreditation cycle and in accordance with the agency retention schedule.

12.2.10 Notification of Customers

When substantive nonconformities occur in casework, it may be necessary to notify the customer of the facts surrounding the event. If necessary, an amended laboratory report will be prepared as soon as possible and provided to the submitting agency. The case file will contain documentation of the technical measures taken to resolve the nonconformity.

12.3 Responsibility for Authorizing Resumption of Work

In cases where an analyst has been removed from casework, or when required by the corrective action plan, a follow-up competency test will be issued by the Quality Process Manager following successful completion of the corrective action plan. An analyst may only return to casework on the authorization of the CLD Commander. If a process or procedure has been removed from use, it also will not be used until authorized by the CLD Commander. Authorization to return to casework from the DNA Technical Leader is additionally required if the actions involve DNA or CODIS.

12.4 Preventive Actions

Preventive actions are designed to eliminate the cause of a potential nonconformity and prevent occurrence. Identification of needed improvements, either technical or concerning the management system, evaluation and implementation of a preventive action may include one or more of the following:

- Research regarding policies and procedures in other crime laboratories or jurisdictions
- Consultation with customers to ascertain the extent of their needs
- Consultation with CLD employees to obtain developmental suggestions
- Validation of technical methods following the Method Validation section of the CLD Quality Operations Manual
- Monitoring of effectiveness with CLD employees and customers of laboratory services

Personnel are encouraged to identify preventive actions as opportunities to improve quality and correct potential sources of nonconformity before they become problems.

Preventive action proposals shall be brought to the attention of the Supervisor, the appropriate technical lead(s) (in addition, if DNA or CODIS, the DNA Technical Leader) for the discipline, Laboratory Manager, appropriate Management Liaison, and/or Laboratory Accreditation Manager through written correspondence such as e-mail or IOC. The Supervisor, Laboratory Manager, and/or appropriate staff shall evaluate the suggestion and work with the submitting individual to develop an action plan. As the preventive action is implemented, it shall be monitored for effectiveness as outlined in the action plan.

13 TRACEABILITY AND QUALITY CONTROL

Many factors contribute to the accuracy and reliability of the tests performed by the CLD, including:

- The training and qualifications of personnel
- Technical/analytical methods
- Reagents and supplies
- The selection, calibration and maintenance of equipment

The CLD will take account of these and other factors and will ensure that the personnel are properly qualified and trained; that procedures are validated; that reagents and supplies are traceable and verified for performance; and that equipment is calibrated and/or verified. All procedures, reagents, supplies and equipment/instrumentation that affect the quality of the tests and/or calibrations will be controlled.

13.1 TRACEABILITY AND QUALITY CONTROL OF REAGENTS

13.1.1 Policy

All commercially and laboratory prepared reagents, as well as chemicals used to prepare reagents, used for casework analysis within the CLD will be of sufficient quality to assure the integrity of the analytical results. All reagents must be checked regularly to ensure their reliability and that the quality will equal or exceed that necessary for the type of testing or use designated in the functional area technical manual. How this will be performed and the frequency of reagent checks will be determined by each functional area and will be found in the respective technical manuals. The reliability testing shall occur before use or, if appropriate, concurrent with testing.

Reagents prepared in the laboratory shall be labeled with, at a minimum, the identity of the reagent, the date of preparation or lot number, and, as applicable, (for example, other than room temperature), storage requirements. Records shall be maintained identifying who made the reagent, the components used in preparation, and that the reagent was tested and worked as expected.

13.2 EQUIPMENT

13.2.1 Policy

Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Before being placed into service for use, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and

complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

13.2.2 Procedure

Equipment will have regular maintenance, calibration (if required) and performance verifications to ensure continued performance.

Laboratory Managers have final approval authority before new equipment is placed into service for casework and must ensure that the validation and/or performance verifications take place.

13.2.3 Personnel Equipment Use

Equipment shall be operated by authorized personnel as determined by the individual lab managers. The lab manager has the responsibility to ensure that authorized equipment user list(s) for their laboratory are updated and available.

Recognizing that there may be occasions where an individual scientist may need access to and use of equipment in another Division laboratory, if the scientist has been given authorization to use similar equipment and software in one Division lab, that authorization may automatically apply to any laboratory using comparable equipment and where appropriate, software.

Laboratory technicians, scientists in a training status and interns will be given authorization commensurate with their level of experience. Each lab manager will maintain documentation of persons authorized to operate the laboratory's equipment used for testing, calibration and sampling. Laboratory technicians and interns must have their training documented and be specifically authorized to operate specified laboratory equipment.

13.2.4 Equipment Identification

Each item of equipment and its software used for testing and calibration and significant to the result shall be uniquely identified.

In laboratories with multiple items of equipment of the same make/model, each item of equipment will be uniquely identified and the identifier will be used in the case documentation, including case notes and hard copy equipment data. In a laboratory with only one item of equipment for a specific test or procedure, the equipment identification is documented in the laboratory equipment list.

13.2.5 Equipment Documentation

Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

Maintenance procedures will include a maintenance plan that indicates the frequency and type of maintenance to be performed (i.e., annual, as needed or by manufacturer). Scheduled manufacturer maintenance contract information (if applicable) will also be retained by the laboratory/discipline.

Each item of equipment and any associated software significant to the tests and/or calibrations performed will have records that are maintained. The records shall include at least the following:

- Equipment identity: type, manufacturer, model, serial number or unique name and current location
- Identity of the item of equipment's software, if applicable
- Original equipment paperwork provided with equipment installation
- Manufacturer's instructions, if available, or reference to their location
- Maintenance plans, where appropriate
- Maintenance procedures and records of maintenance performed
- Date of maintenance, initials of the person doing the maintenance, activity conducted
- Performance verification procedures, or reference to appropriate technical procedures manual
- Documentation of performance verification
- Calibration procedures (as required), including procedures for when intermediate checks are needed to maintain confidence in the calibration status of the equipment
- Scheduled calibration (if required) including dates, results, reports and certificates and the due date of next calibration
- Any damage, malfunction, modification or repair to the equipment
- Internal validation procedure, data and documentation
- List of authorized equipment users

Equipment maintenance, calibrations, and results of performance verifications that are performed will be documented and maintained in an equipment maintenance log. This log will be kept in close proximity to the equipment whenever possible. An electronic log is an acceptable alternative or complement to a written log. Because equipment logs are part of the case record, the equipment log retention time will be the same as for case files. Maintenance/verification logs will be kept with the equipment if the equipment is transferred to another laboratory.

13.2.6 Methods Used on Equipment

The laboratory or discipline will ensure that all methods used on analytical equipment, either newly purchased, or existing equipment that is significantly modified such that the change(s) affects the outcome of the test, or are to be used for new analytical applications, are properly validated prior to being placed in

service for casework in a CLD laboratory. Refer to the section on Method Validation for more details.

A laboratory may adopt a validated method which, e.g. has been published as a standard, or purchase from a qualified vendor a complete measuring system to be used for a specific application. In both these cases, basic validation work has already been carried out. However, the laboratory must confirm its ability to apply the method. This verification requires that some experimental work be completed in order to demonstrate that the method works in the CLD laboratory.

13.2.7 Equipment Data

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

- Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

Laboratory-developed software, commercial software being used outside its intended application, and custom software created by a third party specifically for the laboratory, shall be validated and records of the validation maintained. A validation plan will be developed: the method validation section can be used as a guideline. Commercial off-the-shelf software (e.g. word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated and documented as being adequate for use.

13.3 EQUIPMENT PERFORMANCE VERIFICATION

Equipment to be used for existing applications and methods must be performance verified before use. The laboratory or discipline will ensure that all analytical equipment has their performance verified prior to use. The process will be as extensive as is necessary to meet the needs of the given application or field of application. All performance verifications will be performed by qualified personnel with adequate resources.

Performance verification procedures will include (see also section on Performance Validation for Methods):

- the principle of the verification;
- verification frequency;
- verification tolerances, acceptance criteria
- specific step-by-step verification instructions including the use of any reference standards or reference materials. When possible, all verification will be completed with traceable reference standards or materials.

Performance verification procedures that are completed will be documented in the equipment maintenance log and will include the following:

- Verification date
- Initials of the person performing the verification
- Type of verification performed (e.g. internal diagnostic or comparison to a reference standard)
- Verification results (pass or fail?);
- Identification of reference standard or reference material used
- Any comments regarding performance checks

Upon verifying the performance of a new item of equipment, the Technical Lead or for equipment in DNA, the DNA Technical Leader, will ensure that the performance verification is completed successfully. Upon completion, documentation of the performance verification will be retained in the laboratory. The Technical Lead will prepare an IOC directed to the section supervisor and/or Laboratory Manager, as appropriate, advising them that the equipment has been performance verified and is ready for use in casework. By signing and acknowledging the IOC, the Laboratory Manager authorizes the placing of the equipment into service.

Items of equipment which have previously had their performance verified do not require further authorization by the Lab Manager or the DNA Technical Leader.

13.4 EQUIPMENT CALIBRATION

Equipment requiring calibration will be calibrated prior to being placed into service in a CLD laboratory. Functional areas will have a list of the equipment used in testing that has a significant effect on sampling, the test result, or the total uncertainty of the test result, which require calibration. In situations where the calibration of equipment does not have a significant effect on sampling, the test result, or the total uncertainty of the test result, the laboratory shall have objective evidence to demonstrate the insignificant contribution.

Calibration status will be checked after any unexpected shutdown or removal of the equipment from service and following service or other substantial maintenance.

Calibration checking procedures will be described, where appropriate, in the functional area technical manuals. Calibration procedures shall be established for key quantities or values of the equipment where these properties have a significant effect on the results.

Equipment requiring calibration will have a documented calibration schedule. The recalibration schedule will include the frequency of calibration required, the status of calibration and the next calibration due date. Calibration check intervals will not be less stringent than that recommended by the manufacturer. If a laboratory determines that intermediate checks of the calibration status are needed, the procedure shall define the frequency of the checks. Once established, any extension in the interval of intermediate checks shall be based on documented empirical data and an evaluation of risk. Calibration/recalibration documentation and calibration certifications will be maintained in the Equipment Maintenance log.
Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

Where calibrations give rise to a set of correction factors, the functional area procedures manuals shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.

In situations where the measurements require measurement traceability and calibration of equipment does not have a significant effect on sampling, the test result, or the total uncertainty of the test result, the laboratory shall have objective evidence to demonstrate the insignificant contribution.

When external calibration services are used, traceability of measurement will be assured by the use of calibration services that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these services will contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

If available, suppliers of external calibration services for reference standards requiring calibration (see section below on Traceability of Measurement Standards) and for calibration equipment where the calibration of the equipment has a significant effect on the accuracy or validity of sampling or a test result, or the total uncertainty of the test result, shall be either:

- a National Metrology Institute that is a signatory to the International Bureau of Weights and Measures (BIPM) - CIPM Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database (KCDB)2, or
- a service supplier accredited to ISO/IEC 17025:2005 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC): Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation.

In situations where a supplier of external calibration services that meets the above listed criteria is not available, the laboratory shall confirm competence, measurement capability, and measurement traceability for the supplier and the service being purchased. Objective evidence of the confirmation shall be available for review. Documentation of vendor competence, capability and traceability will be maintained as described in the section on Vendor Evaluation in this manual.

13.5 Equipment Calibration/Certification/Maintenance Schedules

Calibration/Recertification and maintenance for the following general laboratory equipment used in case work will be conducted and scheduled accordingly:

- Scales/Balances will be calibrated at least once per year by a qualified external agency.
- NIST traceable rulers, rods, micrometers, calipers, tape measures and other measuring devices will be recertified before certification expires.
- If calibration is required for pH meters, it will be performed prior to use.
- NIST traceable thermometers and temperature probes will be recertified before their certification expires. For non-NIST traceable thermometers, each functional area that uses them will establish protocols and documentation for temperature monitoring, with periodic checks of the thermometer against a NIST traceable probe.
- Pipettes will have the calibration checked at least once yearly by a qualified external agency.
- Microscopes will be serviced as necessary by qualified microscope technicians. It is recommended that the service interval not be longer than three years. Each laboratory will maintain microscope service and repair records for microscopes in their inventory.

Calibration/recertification and maintenance schedules and procedures for discipline specific equipment will be outlined in the respective functional area technical procedures manuals.

13.6 EQUIPMENT OUT OF SERVICE

Equipment that has been subjected to mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use and clearly labelled or marked as being out of service until it has been repaired and shown by calibration or performance verification checks to perform correctly. In addition, the removal of the equipment from service, date of removal, why the equipment was removed from service, and the date the equipment was placed back in service will be documented in the equipment log.

The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations. If the nature of the malfunction is such that the accuracy of previous reported test results are suspect, the situation shall be immediately brought to the attention of the appropriate Technical Lead, DNA Technical Leader if DNA or CODIS, Section Supervisor and Lab Manager. The Lab Manager will inform the Standards and Accountability Section, and corrective action shall be performed. The laboratory will follow the corrective action process for nonconforming work.

13.7 EQUIPMENT RESPONSIBILITIES

- Forensic Scientists/Lab Technicians assigned equipment responsibilities are responsible for performing assigned equipment validation, performance verification and maintenance and will document all necessary information concerning verification and maintenance activities in the Equipment Maintenance log.
- Forensic Scientists/Lab Technicians are responsible for ensuring that the equipment in use has been properly calibrated or verified prior to use.

Technical Leads are responsible for:

- Preparing and organizing validation studies as needed
- Ensuring that calibration/verification and maintenance procedures are in place for each item of equipment and software determined to require verification and maintenance in their discipline
- Writing and modifying the verification procedures for each item of equipment in their discipline
- Monitoring compliance with calibration/verification and maintenance procedures through periodic spot checks
- Addressing problems concerning verification according to WSP CLD Policy
- Verifying external calibration companies are ISO compliant

Lab Managers/Supervisors are responsible for:

- Ensuring that all users are properly trained and authorized prior to equipment use
- Periodic review of all calibration/verification and maintenance records and activities
- If a problem with an item of equipment is identified, such that the accuracy of previously reported test results is suspect, the Lab Manager/Supervisor shall immediately alert the Standards and Accountability Section and the Technical Lead for that discipline. Lab Managers and Supervisors will ensure that corrective actions take place.

Standards and Accountability Section is responsible for:

- Monitoring compliance with calibration/verification and maintenance procedures through annual audits of logs.

13.8 EQUIPMENT USE OUTSIDE THE LABORATORY

When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

When equipment that is outside of the laboratory's permanent control is used by CLD analysts for reporting results, the analyst must document that the equipment has been properly maintained and controlled.

If analysis is performed by CLD personnel at a laboratory not regulated by the WSP CLD, the following restrictions apply:

- The analysis may be conducted if the outside laboratory can demonstrate that it meets the requirements of ISO. The use of equipment from another laboratory must be documented in the case notes and in the lab report. The outside laboratory must provide validation documentation to demonstrate that the instrument meets the needs of analysis.
- Analysis may be contracted to another laboratory. The contract laboratory will be solely responsible for the content of its own casework report. The referral of evidence to an outside or contract laboratory must have the approval of the submitting agency and the Prosecuting Attorney's office where applicable. Discussions with the submitting agency and Prosecuting Attorney's office should include the limitations and expenses of outside analysis. The CLD lab reports must reflect the referral of the evidence to the other laboratory.
- Convicted offender DNA samples may be contracted out without notification to the collecting agency.

13.9 MEASURING OR CALIBRATION EQUIPMENT

Functional area technical procedure manuals will include procedures, or make reference to procedures, to ensure safe handling, transport, storage, use and planned maintenance of measuring equipment (i.e., balances, pipettes, calipers, trigger pulls, rulers) to ensure proper functioning and in order to prevent contamination or deterioration.

Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

Should the measuring equipment be used outside the permanent laboratory for tests, calibrations or sampling, additional procedures should be considered and included in the procedures as needed.

13.10 TRACEABILITY OF MEASUREMENT STANDARDS

13.10.1 Policy

All test equipment used in CLD laboratories that has a significant effect on the measurement result and their associated uncertainties of measurement, will be traceable to national and/or international standards of measurement. This will be done through the use of a measurement standard. The CLD will safely handle, transport and store these measurement standards in order to prevent contamination or deterioration and in order to protect their integrity.

13.10.2 Procedure

Measurement standards or materials (e.g., thermometers, weights) used to check accuracy of other equipment or instruments shall not be used for other purposes.

All calibrations and adjustments using these standard materials will be documented.

All in-house NIST traceable CRMs must be periodically checked and recertified by an external agency to maintain their NIST traceability. Recalibration or recertification of these materials will take place before their certification expires.

Vendors used for calibration or recertification of these standards shall provide documentation of NIST traceability.

If available, suppliers of certified reference materials used to establish or maintain measurement traceability shall be either:

- a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the certified reference material listed in the BIPM key comparison database (KCDB), or
- an accredited reference material producer that is accredited to ISO Guide 34:20094 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

In situations where a certified reference material producer that meets the above criteria is not available, the laboratory must confirm competence, measurement capability and measurement traceability for the supplier and product being purchased. Objective evidence of the confirmation shall be available for review. Documentation of vendor competence, capability and traceability will be maintained as described in the section on Vendor Evaluation in this manual.

When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. Following service, maintenance and recalibration by such vendors, the certification or documentation provided by them will be maintained in the laboratory.

If mishandling of standard materials brings accuracy into question, the standard materials shall be taken out of service and recalibrated.

To the extent possible, the CLD shall utilize measurement standards that are traceable to SI units of measurement, to certified reference materials, or to other applicable verification sources.

When traceability of measurements cannot be made in or is not relevant to SI units, then measurement standards will establish traceability by one of the following:

- The use of certified reference material from a supplier
- The use of specified methods, published standards, and/or consensus standards
- Participation in inter-laboratory comparisons

Documentation of this traceability to SI units or CRMs and the recalibration/recertification information shall be maintained by the appropriate Laboratory, Laboratory section or the Standards and Accountability Section.

Internally developed measurement standards must be checked against published references or certified reference materials, identified and controlled. Documentation of traceability must be maintained in the laboratory.

13.11 TRACEABILITY OF REFERENCE STANDARDS AND MATERIALS

13.11.1 Policy

Reference standards and materials that are maintained and used in casework for identification, comparison or interpretation purposes (e.g. motor vehicle paints, controlled substance standards, hair samples) shall be fully documented, uniquely identified and properly controlled. In addition, CLD employees will safely handle, transport, store and use these reference materials and standards in such a manner as to prevent contamination and deterioration and to protect their integrity.

13.11.2 Procedure

Each laboratory is responsible for ensuring that their reference standards and materials are fully documented, uniquely identified and properly controlled.

If mishandling of reference standards or materials brings their accuracy into question, the standards or materials shall be taken out of service until accuracy is verified.

Reference materials and standards having an expiration date must be periodically checked and renewed prior to their expiration dates. Expired reference materials may be used as secondary standards, but may not be used for calibration purposes. Expired standards or materials may also be used for non-casework related functions such as validation, training, performance checks, and competencies at the supervisor's discretion.

For many types of analysis, calibration and instrument performance checks may be carried out using laboratory-made standards containing the analytes under test, prepared from chemicals of known purity and composition, or matrix matched standards. Alternatively, standard solutions may be purchased. Many chemicals can be purchased with the manufacturer's statements or certificates. Wherever possible, laboratories should obtain supplies of chemical reference standards from ISO compliant suppliers.

Examples of WSP CLD Reference Standards include:

- FTIR NIST traceable polystyrene Reference Standards
- Mass Spec NIST traceable perfluorotributylamine (PFTBA) Reference Standard
- Glass Reference Standards

Examples of WSP CLD Reference Materials include:

- Ignitable Liquid Reference Materials
- Drug Reference Materials
- Fiber Reference Materials
- PDQ Motor Vehicle Paints – Reference Material
- Firearms Reference Collection

13.12 DRUG REFERENCE MATERIALS

The policies and procedures regarding the Drug Reference Materials are described in the Drug Reference Materials section of the Materials Analysis Technical Procedures Manual.

13.13 INDIVIDUAL CHARACTERISTIC DATABASES

13.13.1 Policy

All individual characteristic database samples under the control of the CLD will be treated as reference materials. Individual characteristic database samples under the control of the CLD include known biological samples from convicted offenders (CODIS).

13.13.2 Procedure

Whenever possible, all samples will be treated in a manner that reasonably ensures their utility as reference materials. In general this will consist of:

- Maintaining control of samples utilizing a unique identifier. Agencies contributing to individual characteristic databases may use various methods to accomplish uniquely identifying database samples;
- Protecting the samples from loss, cross transfer, contamination and/or deleterious change. Individual characteristic database samples must be treated in a manner that maintains their use as reference materials;
- Restricting access to those persons authorized by the Laboratory Manager. The laboratory manager shall authorize access to those individuals having a legitimate purpose and maintain that list in the laboratory for review by auditors. Such persons include, but are not limited to, individuals responsible for database maintenance and administration and equipment repair. These individuals may or may not be under the control of the laboratory. Documentation of access to the CODIS database will be maintained by the state CODIS administrator;
- Each unit that utilizes an individual characteristic database will be responsible for preparing and using a protocol for handling and storing such reference material as it relates to individual characteristic databases, taking into account the special needs of the unit. These protocols must be described in the functional area technical manuals.

13.14 OTHER DATABASES

13.14.1 Policy

The CLD maintains other databases for the cataloging, storing and retrieval of quality and technical information. Access to these databases will be limited to authorized staff. Administration and changes to these databases will be by designated individuals only. Laboratory Managers will designate an individual or individuals for the management and administration of the laboratory specific databases.

The CLD databases will be managed by the Quality Process Manager or designee. The local CODIS DNA database (LDIS) will be administered by the local CODIS administrators. The State DNA database (SDIS) will be administered by the CLD CODIS Laboratory Manager. The CLD LIMS database will be administered by the FLSB IT Manager.

Other databases include but are not limited to:

- Laboratory Chemical Inventory Database (All laboratories)
- Laboratory training samples collections
- Laboratory Key Inventory Database (All laboratories)

13.15 MEASUREMENT UNCERTAINTY

13.15.1 Policy

The CLD will have and apply procedures for estimating the measurement uncertainty for reported quantitative test results, where required. The discipline procedure will attempt to identify all the components of uncertainty and make a reasonable estimation to ensure that the form of reporting the result takes into consideration any applicable measurement uncertainty.

13.15.2 Definitions

13.15.2.1 Significant Figures

Significant figures are those digits between and including the least and most significant digits in a number. The leftmost nonzero number is the most significant. The rightmost nonzero number is the least significant digit. If a decimal point is in the number, the rightmost digit is the least significant even if it is a zero.

13.15.2.2 Bias

The difference between a measurement result and the true or target value of the property being measured. The bias can be absolute or relative. The bias quantifies the accuracy of the measurement.

13.15.2.3 Coefficient of Variation (cv)

The relative standard deviation expressed as a percentage; another way to quantify the precision of measurement.

13.15.2.4 Measurement Uncertainty

The property associated with a measurement result that characterizes the dispersion of the values that could reasonably be attributed to the true value being measured.

13.15.2.5 Standard Uncertainty

The uncertainty of a measurement result expressed as a standard deviation.

13.15.2.6 Expanded Uncertainty

A multiple of the standard uncertainty which provides an interval within which the true quantitative result is expected to lie with a stated level of confidence. For a multiple of k=2, the interval will yield approximately 95% confidence that it contains the true property being measured.

13.15.2.7 Confidence Interval

A confidence interval gives an estimated range of values which is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data (Definition take from *Valerie J. Easton and Johns H. McColl's Statistics* Glossary v1.1).

13.15.3 Procedure

Measurement Uncertainty is a parameter associated with a measured result that characterizes the possible range of values that could, under a specified level of confidence, be attributed to the result or method. In other words, the Measurement Uncertainty is used to indicate the degree of variability, at a specified level of confidence that can be expected for that particular measurement or method.

Measurement uncertainty takes into consideration all the potential variables that contribute to the measured result. Sources contributing to the uncertainty may include, but are not limited to, the reference standards or materials used, the procedure or equipment used, the environmental conditions, the properties or condition of the item being tested and the analyst performing the test. All components that may contribute to the measured uncertainty will be taken into consideration when estimating the measurement uncertainty.

Quantitative measurements: the measurement uncertainty shall be determined for quantitative measurements, such as weights of controlled substances.

Qualitative procedures such as identifying the presence or absence of a controlled substance or biological fluid, firearm operability and firearm/tool mark identifications (bullet or cartridge comparisons, etc.) do not require an estimate of measurement uncertainty.

The following test procedures have been identified as requiring an estimate of measurement uncertainty:

- Firearm barrel length determinations
- Marijuana weights
- THC concentration

The affected functional area technical manuals will detail the procedures describing how the measurement uncertainty is calculated and how it must be applied when reporting the result.

13.15.4 Significant Figures and Truncating Values

The number of significant figures must, at a minimum, correspond to the uncertainty in the measurement and must not be more than the precision of the measuring device. If truncation is required for reporting purposes, truncation will occur after calculation to the appropriate significant figures and calculation of the measurement uncertainty.

13.15.5 Reporting Measurement Uncertainty

When measurement uncertainty is required, the case notes must contain the uncertainty of measurement or a reference to it. When this measurement uncertainty is of significance to the requestor, the range of values and the attendant uncertainty will be reported with specific confidence limits. Reports of analysis shall not overstate certainty of findings. The reported uncertainty statement shall:

- include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;
- be in the format of $y \pm U$ with the units of y and U being consistent;
- limit the rounded expanded uncertainty to at most two significant digits, unless the laboratory has a documented rationale for reporting additional significant digits; and;
- require the rounded expanded uncertainty be reported to the same level of significance as the measurement result.

14 ACQUISITION OF SERVICES, SUPPLIES AND EQUIPMENT

14.1 POLICY

All purchasing, ordering and payment procedures will comply with WSP Budget and Fiscal Services (BFS) requirements. Such requirements are set forth in the Budget and Fiscal Services SOP and are found on the BFS Intranet website. The CLD is responsible for the acquisition, custody and disposal of all property within its control; therefore the CLD should only acquire property necessary to fulfill its mission. Division equipment and property will not be used for personal purposes.

Supplies and services that affect the quality of tests shall be selected and purchased at a quality appropriate for the analysis.

Each functional area or discipline shall maintain specifications for supplies and materials that affect the quality of their tests within the testing methods of their procedural manuals. Reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability shall be viewed as critical, affecting the quality of the tests.

All equipment will be kept secure from damage, misuse, misappropriation, and theft. All equipment must be maintained in proper working condition. Equipment needing repair must be brought to the attention of the section supervisor who will inform management as necessary.

Equipment will be selected on the basis of its appropriateness for specific functions, initial cost, ongoing support costs, and the availability of funds for equipment purchases and maintenance.

Records shall be kept that demonstrates the receipt of supplies to include the ordering and acquisition date, and the receiver. Each laboratory shall ensure that standards, controls and reagents used in technical procedures are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests concerned, or tested prior to use. Other recognized standards, e.g., testing of the delivered product or service, may be used at the discretion of the laboratory.

The laboratory shall evaluate all suppliers of materials (reagents and supplies), services and equipment affecting the quality of tests ensuring that specific requirements and standards of quality are met. A list of evaluated and suitable approved suppliers shall be maintained by the QP Manager, along with their record of compliance with established specifications.

14.2 PROCEDURE

14.2.1 Ordering and Purchase Approval

Data describing the type, class, grade, precise identification, specifications or other technical data including quality required of supplies to be ordered will be reviewed prior to purchase to ensure that the quality of the reagent or supply is appropriate for the analysis.

Only CLD approved vendors for the purchase of supplies and services will be used.

An order will be placed with a supplier only after the supervisor, laboratory manager or their designee has authorized the order in writing or by email. Prior to placing an order, it will be assigned a purchase order number or other approved means of payment to be provided to the vendor if needed, and then used for tracking the order. A system shall be used for monitoring supply orders.

While the CLD Commander is responsible for the CLD budget, laboratory managers are authorized to approve purchases totaling up to $5,000 per order, and supervisors are authorized to approve purchases totaling up to $1,500 per order. (Shipping, handling, and taxes are not included in the limit). Persons who are designated to be in charge may sign for the manager by using the following:

_____ by _____

Manager's Name Signature of Person in Charge

Laboratory Managers and/or office managers will designate:

- Person(s) responsible for placing orders;
- Person(s) responsible for receiving orders and verifying that they are complete and correct;
- Person(s) responsible for tracking orders from time of placement through preparation of payment vouchers.

Laboratory managers must ensure that payment documents are prepared, and that any other purchasing-related responsibilities are fulfilled. Detailed instructions for preparing the various payment documents are included in the Budget and Fiscal Services Procedures Manual.

14.2.2 Receiving Supplies and Services

Upon receipt, supplies, reagents or services will be checked or verified as complying with the purchase request. This can be done by checking the packing slip against the purchase request and against what was actually received to ensure all are in agreement.

If the shipping documents or labels do not match, the supplies or material will not be placed into service until the problem is resolved. Any discrepancies in the order will be recorded on the order documents. In addition, if the resolution includes returning the item, this will be noted on the shipping documents.

The person receiving the material will indicate the following information on the packing slip or receipt:

- The date received (Example: "Rcv'd 1/10/17")
- An indication the appropriate item and quantity were shipped
- Approval will be indicated by the receiver's initials
- The packing slip or receipt will be attached to the order document. Both will be retained for a minimum of one year in the laboratory for future reference.

Purchased supplies will not be placed into service until they have been verified per procedures in the technical manuals.

If an item or product that affects the quality of their tests has been put in use is found to be defective (e.g., not the expected quality) the following shall occur:

- The supervisor or technical leader will assess the item/product for suitability.
- If the product/item has or may damage instrumentation or a process, then the supervisor/technical lead will immediately contact the QP Manager who will alert all possible users.
- A supervisor/technical lead will assess the damage and contact the responsible company for replacement of the product/item and/or possible reimbursement for damages.
- Review of any cases that may have been affected will be conducted. See the section on Nonconforming Work and Corrective Actions.
- The laboratory manager will keep a record of any defective products and take this into account when preparing their review of suppliers as well as considering any future purchases.
- CLD personnel have the responsibility to inform their immediate supervisor of a problem with product or services received from a vendor.

14.2.3 Storage of Reagents and Laboratory Consumable Supplies

At a minimum, reagents and lab consumable supplies should be stored according to manufacturer/vendor recommendations. See the CLD Safety Manual for guidelines.

Each Laboratory Manager or their designee shall maintain a computerized inventory of all chemicals kept in the laboratory. That inventory shall be reviewed and/or updated once per year. Safety Data Sheets (SDS) shall be readily available to all personnel.

14.2.4 Vendor Evaluation

The list of approved suppliers of reagents, supplies and services that affect the quality of testing is on the FLSB Portal. A vendor evaluation for new suppliers of reagents, supplies and services, including proficiency test providers, shall be conducted by the purchaser with information provided to the QP Manager or designee. The vendor evaluation should be based on the following criteria:

- The vendor is currently an ISO certified supplier, is ISO registered or can demonstrate ISO compliance.
- Quality of product/service provided by vendor as related to documented requirements in discipline-specific technical procedures or quality manuals and the Quality Operations Manual.
- Conforms to recognized standards for providing quality goods and services to the State of Washington.

This conformance can be determined by examining the record for past successful performance for the individual laboratory, the laboratory system, or to other government entities. A record of successful past performance meets the requirement for conformance to recognized standards for providing products and services of acceptable quality to the CLD.

A Vendor Approval request, copies of national accreditation documents or a memo covering these points for each vendor shall be prepared by the purchaser and forwarded to the QP Manager. This information may be transmitted electronically.

Vendors providing Calibration Services or Certified Reference Materials will be evaluated annually to ensure current accreditation or certification and appropriate Scope of Accreditation. The Quality Process Manager will be responsible for these annual evaluations.

14.2.5 Acquisition and Retention of Donated Items

Donated items, which may include items that were previously evidence, may be acquired for laboratory purposes but must comply with the following rules:

- Evidence donated to the CLD must be accompanied by written disposition from the donating agency;
- The documentation will include the following information:
    - Date of transfer
    - Name of person releasing property,
    - Name of employee acquiring property,
    - Description of the item(s) including identifiers (serial number, etc.) if applicable,
    - Signature of person acquiring property,
    - Purpose for acquiring the property
- This documentation must be retained until the item is disposed of.

Copies of this receipt will be made available to all parties in the acquisition. Receipts will be retained until the item is disposed of or consumed.

14.3 SECONDARY DRUG REFERENCE MATERIALS

The retention of secondary drug reference materials from casework samples or other non-certified sources will be allowed when there is no primary source reference material commercially available, or when there is a sufficient quantity of material in the case item such that taking a small sample will not consume more than half the original sample amount. These drug samples will be used primarily for training purposes.

To retain a sample from casework, the following procedure must be followed:

- The section supervisor must approve taking a portion of the casework material and the requesting scientist must obtain written permission from the submitting agency prior to removal of the sample. The written permission becomes a permanent part of the case file;
- The sampling must be witnessed by another scientist and will be documented in the case notes which will show the initials of the scientist and witnessing scientist, date, item number, and amount of sample removed. A notation will be made in LIMS regarding the sample having been removed from the drug item;
- The secondary drug reference material must be documented in the drug database and must be verified in the same manner as primary drug reference materials before being used in casework. The verification procedure is detailed in the Drug Reference Materials section of the Materials Analysis Technical Procedures Manual. A copy of the written permission from the submitting agency to remove the material from the case will be retained with the verification data.

14.4 TRANSFER AND DISPOSAL OF PROPERTY/EQUIPMENT

Transfer and/or disposal of property/equipment will follow policies established by the WSP Inventory Control Officer and WSP Regulation Manual. Retention of any equipment no longer serviceable (such as instruments retained for parts) must be approved by the Laboratory Manager.

15 INVENTORIES AND REFERENCE COLLECTIONS

In order to facilitate daily operations and ensure quality compliance certain inventories and reference collections need to be maintained.

Inventories are subject to audits and as such need to be documented and controlled.

Reference collections shall be maintained, fully documented, uniquely identified and protected from unauthorized access.

15.1 INVENTORIES

15.1.1 Inventory of Keys/Key Log

Each Laboratory Manager, or designee, shall conduct an inventory of the keys to the laboratory to verify the accuracy of the key log records and correct any discrepancies. The inventory will be conducted annually. A copy of the verified inventory shall be retained for review during the annual audit of that laboratory.

15.1.2 Inventory of Equipment and Instruments

The accountability for control of equipment and supplies in a laboratory lies with the Laboratory Manager. Inventories of laboratory equipment are maintained by WSP Supply and periodic inventory audits will be required per Supply's schedule. A copy of the verified inventory shall be retained for review during the annual quality audit for that laboratory.

Each Laboratory Manager shall insure that State Identification Number Tags appear on fixed asset items which require such tags, as set forth by the WSP Supply Section. If a laboratory receives such an asset but it does not have a tag, the Laboratory Manager will request a tag from the WSP Supply Section. All fixed assets are subject to inventory.

15.1.3 Inventory of Library Materials

The accountability for control of library materials rests with the FLSB Librarian. The FLSB Librarian will maintain a current, updated inventory housed within the laboratory. Library material information will be entered in the Bureau Library Database in the FLSB Portal when received.

15.1.4 Chemical Inventory and SDS Check

The accountability for control of chemicals in a laboratory lies with the Laboratory Manager. To that end, Laboratory Managers, or their designees, will maintain a current database of all chemicals in the laboratory. The database will include approximate quantities of chemicals present along with their location. See also section on Purchasing Critical Services and Supplies.

Each Laboratory Manager, or designee, shall conduct an annual inspection of the database to verify all chemicals have been entered into the database. A copy of the verified inspection, including the date of inspection, shall be retained for review during the annual audit for that laboratory.

Chemicals no longer needed will be discarded. The section supervisor, in conjunction with the laboratory safety officer, will be responsible for proper disposal of all chemicals. SDSs will be retained for all chemicals on site, and chemicals will be stored according to their safety requirements.

15.1.5 Vehicles

The accountability for control of vehicles assigned to a laboratory lies with the Laboratory Manager. To that end, each Laboratory Manager, or their designee, will regularly maintain the lab vehicles according to the WSP Vehicle Maintenance Schedule or according to the manufacturer's service recommendations, to ensure the estimated life expectancy of the fleet. Regulations pertaining to fleet vehicles assigned to the laboratory are found in the WSP Regulation Manual Chapter 17 and on InsideWSP under the Fleet Section.

Vehicles are tracked and monitored by the Fleet Section. Maintenance records will be retained in each laboratory as needed. Managers shall be responsible for monitoring vehicle repairs and costs by periodically reviewing maintenance files and ensuring accuracy is maintained. A copy of all invoices and purchasing card receipts for vehicle maintenance and repairs will be entered into BMC Remedy in the Vehicle File system as described in Fleet Section procedures.

15.1.6 Special Reference Collections

The CLD maintains several reference collections, including ignitable liquids, minerals, paints and fibers. Specific collections requiring annual audits are described below.

15.1.6.1 Drug Reference Materials Collection

The policies and procedures regarding the Drug Reference Materials collection including annual inventories are described in the Drug Materials Standards section of the Materials Analysis Technical Procedures Manual.

15.1.6.2 Firearms Reference Collections

The policies and procedures regarding the Firearms Reference Collections, including annual inventories, are described in the Firearms/Toolmarks Technical Procedures Manual.

15.2 CONTROL OF OTHER VALUED GOODS

15.2.1 Travel and Purchasing Credit Cards

All Travel and Purchasing credit cards shall be under the control of Laboratory Managers or their designees, and kept in secure locations within the laboratory. Credit card use will be documented, with the receipts for all purchases signed by the user pursuant to WSP Budget and Fiscal Services SOP guidelines. Travel cards may be assigned to specific individuals when appropriate.

16 AUDITS AND MANAGEMENT SYSTEM REVIEWS

16.1 POLICY

All laboratories will be audited annually to verify that operations are in compliance with established CLD policies, ISO requirements, any supplemental document requirements, the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, Quality Assurance Standards for DNA Databasing Laboratories, and applicable WSP policies, rules and regulations. Internal and external audits will be documented and documentation will be retained for at least one cycle of accreditation (four years).

In addition to the annual internal quality audit, an annual Management System Review of the CLD management system's operations for the previous year will be conducted. Testing activities will be reviewed to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements.

The Management System Review, internal and external audit reports along with any nonconformance and corrective action plans will be documented and retained at least through one cycle of accreditation (four years).

Additional audits, such as a focus review, may be requested by the Laboratory Manager, SAS Manager, Laboratory Accreditation Manager, CLD Commander or the FLSB Director at any time. The DNA Technical Leader or discipline Technical Leads with SAS Manager's approval may conduct on-site technical audits to make recommendations for improvement in a specific discipline.

16.2 PROCEDURES

16.2.1 Internal Audits

Each ANAB accredited laboratory will undergo an annual internal audit. The audit report will be addressed to the CLD Commander and submitted to the Laboratory Accreditation Manager along with supporting audit documentation. The Laboratory Accreditation Manager will submit internal audit reports to the accrediting body by the due date established by the accrediting body.

Audits will include on-site inspections of laboratory facilities and will address all elements of the quality system including testing activities. Audits will include a review of the previous year's corrective actions to confirm effectiveness and continued compliance. Internal audits shall include direct observation of a sampling of testing within each discipline.

Audits will be conducted by trained, qualified personnel who are, wherever resources permit, independent of the activity to be audited. Auditors may come from the CLD or from outside the Division.

The SAS Manager is responsible for assuring internal audits and other audits are planned, organized and completed as required by the schedule. The SAS will plan, organize and direct the audits. The DNA Technical Leader organizes and directs the DNA internal audits. The Laboratory Accreditation Manager will have oversight of nonconformances, CARs and follow-up activities, including verifying and recording the effectiveness of any corrective actions taken.

A summary report of internal or external audits of the DNA functional area and CODIS will be prepared by the DNA Technical Leader and submitted to the CLD Commander.

16.2.2 Management System Review

An annual management system review of the CLD management system's operations for the previous year will be conducted in the first quarter of the calendar year.

The Twelve Elements of the Management System Review (MSR)

The annual MSR will address the following points:

1. The suitability of policies and procedures
2. Reports from managerial and supervisory personnel
3. A review of the annual internal laboratory audits
4. Corrective and preventive actions taken in the last year
5. Quality System assessments performed by external organizations
6. The proficiency test program
7. Changes in the volume and type of work
8. Customer feedback
9. Quality system complaints
10. Recommendations for improvement
11. Other relevant factors such as quality control activities, resources, and staff training
12. A review of the overall objectives of management system policies

The results of the MSR will be considered by the CLD Commander for planning purposes. Items from the MSR used for planning purposes will have goals, objectives, and action plans.

A summary report of the annual MSR will be prepared by the SAS Manager and directed to the FLSB Director with courtesy copies to all CLD lab managers.

Implementation of corrective actions initiated from the MSR will be followed up to monitor effectiveness by the SAS Manager within an appropriate timeframe determined by the lab managers during the MSR and also reviewed at the following year's MSR.

16.2.2.1 Audit and MSR Corrective Actions

Any findings of nonconformance from the annual MSR and external or internal audits will be addressed through the Corrective Action Process. Documentation of the finding(s) and corrective action plans are recorded in RNTP, unless otherwise required by an accrediting body.

17 ASSURING THE QUALITY OF TEST RESULTS

17.1 POLICY

The CLD is committed to providing the best quality service available to all members of the criminal justice system. A key component to providing high quality service is through a documented proficiency testing program. While proficiency testing is an integral part of an effective quality assurance program, it is not the sole indicator of satisfactory performance or delivery of a quality product. Proficiency testing does not replace high-quality work, standards, controls, and other conventional quality assurance practices.

The CLD may use, but is not limited to the following for monitoring the validity of tests performed:

- Certified or secondary reference materials and collections
- Positive and negative controls
- Replicate testing
- Orthogonal methods
- Repeat testing (re-examination)
- A documented proficiency testing program
- Technical reviews, including inter-lab technical reviews

The monitoring will be planned and any resulting data will be recorded and reviewed.

17.2 PROFICIENCY TESTING

17.2.1 Definitions

17.2.1.1 Approved Proficiency Test Provider

An individual, organization or company that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA6 and has the applicable proficiency test(s) on its scope of accreditation, or where not available or not appropriate for the testing conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed.

17.2.1.2 Proficiency Test

A proficiency test is an internal or external test that is provided to evaluate the capability of analysts, technical support personnel and the quality performance of a laboratory.

17.2.1.3 Proficiency Review Committee (PRC)

A committee of individuals appointed by ANAB/ASCLD/LAB, because of their experience and expertise, to provide oversight for ANAB/ASCLD/LAB in the proficiency testing program for specific forensic disciplines.

17.2.1.4 Proficiency Test Evaluation Form

The form used to provide comments on an individual's proficiency test.

17.3 PROCEDURE

The CLD proficiency program will be directed by the Quality Process Manager and shall be in compliance with the CLD accrediting body proficiency testing program. Appropriately accredited proficiency test providers will be used where available. Before ordering proficiency tests, the Quality Process Manager will confer with the laboratory managers and supervisors of each laboratory to determine the numbers and types of tests needed.

The CLD proficiency program requires that expected proficiency test results are not known or readily available to the test taker. Each laboratory must successfully complete, per calendar year, at least one external proficiency test with authorized release of the test results to ANAB from the test provider for each discipline in which it provides accredited services. If application for accreditation has been made for a discipline (for example, scope expansion), the laboratory will successfully complete at least one external proficiency test for each discipline in which application for accreditation has been made.

Each scientist/technician within the CLD will complete at least one proficiency test per calendar year in each discipline in which the scientist performs casework. Scientists in the DNA and CODIS functional areas and other personnel designated by the DNA Technical Leader will complete two external proficiency tests each year. Individuals involved in serology screening for biological evidence only will undergo annual external proficiency testing. Individuals involved in outsourced DNA analysis technical review only will complete two external proficiency tests each year. Additional information for DNA proficiency testing is described in the DNA Quality Assurance Manual. Additionally, at least once in a four year accreditation cycle, any person conducting testing must be proficiency tested in all aspects of casework on their laboratory's Scope of Accreditation in which they perform testing.

DNA analysts and technical support personnel performing DNA analysis shall comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

Each laboratory shall have a proficiency testing plan, overseen by the Quality Process Manager, that demonstrates conformance with the proficiency testing requirements stated above and ensures inclusion of a representative sample of the types of tests within each discipline listed on the laboratory's scope of accreditation.

The objectives of the proficiency testing program are to:

- Demonstrate the current competence of the scientist and technical support personnel
- Demonstrate the current competence of the laboratory
- Ensure that quality work is being maintained
- Identify areas where additional training or resources would be beneficial
- Verify the validity of technical procedures

17.3.1 Proficiency Test Samples

Proficiency test samples will be handled in the same manner as case evidence until the Quality Process Manager determines that all proficiency test requirements have been satisfied and the sample is no longer needed for that purpose. The sample may then be kept as a training sample, or it may be destroyed as determined by the supervisor or Technical Lead. The final disposition of the sample must be documented by the supervisor in LIMS. An exception to the documentation of final disposition would be those proficiencies in which a physical sample does not exist, such as data found in a website link.

For internal proficiency tests samples, the CLD may use internally created practical tests, previously worked or older unworked commercially provided practical tests, testing reanalysis, external tests whose results are not submitted to the test provider or not authorized for release to ANAB and when appropriate, observation based tests. When an internal proficiency test sample is internally created or is a previously used proficiency test sample being used a second time, the quality of the test sample must be ensured prior to issuing the test. The analyst performing the proficiency test must ensure a previously used test is in good condition, has does not exhibited deleterious change, and is of sufficient quantity. Results of the first and second testing will be compared and evaluated as described below: if there is a significant difference between the analyst's proficiency test results, the reason will be investigated with appropriate follow-up action (such as another test) taken. For test samples internally created but not previously tested or used as part of a testing process, the quality of the test sample shall be confirmed by examination of the test sample by a scientist authorized to perform the testing.

17.3.2 Proficiency Testing Process

The Quality Process Manager will keep records regarding how the test samples are obtained or prepared, as well as completion dates and results of the testing. As tests are received, the Quality Process Manager will disperse the necessary tests to appropriate labs. The laboratory manager and/or supervisor are responsible for assigning proficiency tests to their scientists as needed. The Quality Process Manager will ensure that appropriate proficiency test samples are obtained, assigned, and provided to each scientist with enough advance notice to allow completion prior to deadlines.

Proficiency tests must be completed and the results submitted to the test provider within the timeframe imposed by the provider. This requirement is essential to the overall success of the CLD Proficiency Testing Program; therefore it is the responsibility of the scientist assigned the test to ensure that this requirement is met.

Management has the responsibility to see that the proficiency test is assigned to and received by the scientist in a reasonable time frame. The scientist must perform the testing so that there is sufficient time to accomplish appropriate reviews for the test results to be sent to the test provider by the due date.

The scientist will document and report to their supervisor, laboratory manager, and the Quality Process Manager if a proficiency cannot be completed by the deadline. It is the responsibility of the laboratory managers and supervisors to ensure that proficiency results are completed and returned to the test provider.

Proficiency tests must be completed in the same manner as casework using approved test methods and be consistent with the respective analysis and reporting procedures of the category of testing. The proficiency test results will undergo technical review and administrative review before results are sent to the test provider. The technical review will be documented in LIMS and by the reviewer's initials and date on a copy of the answer sheet or in the electronic case file.

The administrative review will be documented in LIMS and may additionally be documented on the answer sheets. The administrative review documents that the answer sheet for the proficiency test has been fully completed and is free of errors.

Proficiency test case files contain a copy of the answer sheet with the assigned scientist identified, case numbers, date of completion, and documentation of technical review.

Copies of the answer sheets with the assigned analyst's identity and other necessary paperwork, including confirmation of submission to the provider, for the proficiency test will be sent to the Quality Process Manager.

The Date of Completion for the proficiency test will be the date when the results/answer sheets are submitted to the proficiency provider. If the responder is not submitting to the proficiency provider, the completion date will be the receipt of the answer sheet by the Quality Process Manager.

The intent of the proficiency testing program is to identify individual technical issues and also systemic issues. Therefore, if a technical reviewer disagrees with the conclusions reached by a scientist, then it is incumbent upon the reviewer to bring the problem to the attention of the scientist and their supervisor. The procedure used to resolve technical review conflicts in actual casework as outlined in this manual will be followed.

When the results of the proficiency tests are received, the Quality Process Manager or designee will review the scientist's and the provider's results. The Technical Lead/DNA Technical Leader of each discipline will be involved, as much as possible, in the evaluation of the proficiency answer sheets for technical accuracy. The scientist's results will be compared to the proficiency test provider's results (manufacturer's specification and answer information) and evaluated for technical accuracy and agreement. The scientist's supporting documentation (notes) may additionally be compared and evaluated. For proficiency tests involving quantitative analyses, such as THC quantitation, results will be acceptable if the reported results are within two standard deviations of the assigned value of the analyte or within the satisfactory range as defined by the statistical analysis reported in the test result summary.

Proficiency test records will be maintained at CLD Headquarters. Proficiency test records include:

- Proficiency test unique identifier
- How tests were obtained or created
- Discipline tested
- Written instructions for completion
- Identity of person taking the test
- Location where the proficiency test was taken
- Due date and completion date
- Copy of the proficiency test report (answer sheet(s)) and records submitted to the test provider
- Expected proficiency test results
- Copy of the proficiency test evaluation form
- Documentation that feedback was provided to the analyst
- Any discrepancies noted
- Details of corrective actions taken (when necessary)

The proficiency test records maintained in the case file shall also include all data and notes supporting the conclusions.

Proficiency test records will be retained at CLD Headquarters for at least one full accreditation cycle. After this time they may be archived with the same agency retention schedule as case files.

Test items, except for controlled substances, may be stored in the appropriate functional area with other training materials. This will be documented in LIMS by releasing the item to a location outside of the evidence vault, within the laboratory.

Completed drug analysis proficiency samples, when stored outside of the vault, must be stored using the same precautions and levels of security used for other controlled substances such as drug reference materials. This will be documented in LIMS by releasing the item to a controlled storage location.

If the drug analysis proficiency samples are to be destroyed, the destruction of the samples must be documented using a WSP Property/Evidence Report form 3000-110-096. The item to be destroyed will be sealed in an appropriate package, assigned a WSP Property/Evidence number, and signed over to a WSP District PEC. Copies of the WSP Property/Evidence Report that contain the signature of the releasing scientist and the WSP District PEC will be retained for at least one accreditation cycle and the destruction of the samples documented in LIMS by transferring the evidence to the “destroyed” location.

17.3.3 Satisfactory Proficiency Test Results

If the test results are satisfactory, the Quality Process Manager will complete documentation of the satisfactory result in the records. Documentation of satisfactory

completion will be issued to scientists, their laboratory managers, and supervisors. The documentation shall be initialed and dated by the analyst performing the proficiency test before inclusion in the case file.

17.3.4 Proficiency Test Discrepancies

If there is a discrepancy between the scientist's test results and the provider's results, the Quality Process Manager will notify the laboratory manager, supervisor, Technical Lead or DNA Technical Leader as applicable, and scientist who performed the test. The laboratory manager may subsequently receive a Letter of Inquiry from the ANAB/ASCLD/LAB Proficiency Review Committee (PRC). The Letter of Inquiry shall immediately be forwarded to the Quality Process Manager. The SAS, in collaboration with the supervisor, Technical Lead/DNA Technical Leader, and/or laboratory manager will determine a course of action. The Management Liaison may also be involved if necessary.

Responses are required on all Letters of Inquiry and should be directed to the PRC contact person identified in the letters. A Request for Additional Information and the Referral Letter are communications that could be received after the PRC has reviewed the laboratory's response to a Letter of Inquiry.

If there is a test response different from the expected and consensus response, the laboratory manager may receive a "Notification" from the ANAB/ASCLD/LAB PRC. The Notification does not require a response to the PRC. The purpose of the Notification is to ensure that the laboratory is made aware of the test response difference. The Quality Assurance Manager, in collaboration with the supervisor, Technical Lead/DNA Technical Leader, Laboratory Accreditation Manager, and/or Laboratory Manager will determine a course of action. The Management Liaison may also be involved if necessary. There is no need for a laboratory to respond to a Notification unless the test results were not correctly transcribed and summarized by the proficiency test provider. The laboratory shall retain the Notification with the proficiency test file, the DNA Technical Leader (only if DNA related), and the Quality Assurance Manager.

If other quality/procedural concerns are raised during the proficiency process, the Quality Process Manager may issue a Proficiency Test Inquiry form (CLD Form 4017) for more information. In lieu of the form, the Proficiency Test Inquiry may be entered and tracked in RNTP. The request for information will be provided to the scientist, supervisor, lab manager, and the appropriate Technical Lead/DNA Technical Leader, and the SAS Manager. The Management Liaison may also be involved if necessary. The SAS Manager will make the determination if a nonconformance has occurred and if a corrective action investigation is necessary. This approach is similar to the Letter of Inquiry or Notification Letter issued by the ANAB/ASCLD/LAB Proficiency Review Committee.

If a scientist's performance on a proficiency test requires further development to meet quality standards, the SAS Manager, in collaboration with the scientist, supervisor, Technical Lead/DNA Technical Leader, and/or laboratory manager will determine a plan of

action which shall include removal of the scientist from casework in the area in which the proficiency was performed and remedial training. The Management Liaison may also be involved if necessary. The SAS Manager will prepare a report to the CLD Commander outlining the issues and the actions taken. The SAS Manager or designee will then draft a response from the division to the PRC indicating the actions taken. The CLD Commander will review and approve the final draft. Once approved, the response will be sent to the PRC.

The proficiency test case file will contain a record of the discrepancy between the scientist's test results and those of the test provider. The Quality Process Manager will retain complete records for the CLD.

17.3.5 Proficiency Testing and Job Performance

Satisfactory performance on a proficiency test should be documented in the employee's supervisory desk file. Likewise, any problems identified from the review of a proficiency test, if reflective of difficulties with a scientist's individual work performance, will be addressed by the supervisor and documented in the scientist's supervisory desk file. The supervisor may enlist input and assistance from the Technical Lead or DNA Technical Leader, the Quality Assurance Manager, the Laboratory Accreditation Manager, the Laboratory Manager, the Division Commander, and other appropriate individuals. See sections in this manual on Nonconforming Work and Corrective Actions and Documenting Job Performance.

18 TECHNICAL PROCEDURES AND METHODS

18.1 POLICY

The CLD will use appropriate technical procedures and methods that have been scientifically validated and accepted for use in the field of forensic science. This includes methods and procedures for the sampling, handling, transport, storage and preparation of evidence items, the operation of all relevant equipment having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling, and an estimate of the measurement uncertainty where appropriate. All methods and procedures will be documented and readily available for review by laboratory personnel. Any deviation from a standard technical procedure or method will require that the details of the modification as well as the justification and the authorization be documented in the case notes and maintained as a permanent part of the case file.

18.2 TECHNICAL PROCEDURES

Technical procedures must be based upon sound scientific principles and as effective and efficient as possible. Every procedure used must be generally accepted in the relevant scientific field. All test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations (DNA), prior to comparison to one or more known item(s). Characteristics and their comparison criteria are described in the discipline technical procedure manuals. This requirement is not focused on the process of screening an unknown in order to identify evidence or characteristics that may be the subject of further comparison. In these cases, it may be appropriate to perform a preliminary characterization of the known sample prior to the assessment of the unknown.

An additional criterion for the selection of a technical procedure is general acceptance by the appropriate functional area group within the division. Even though a technical procedure may have gained general acceptance within the relevant forensic science community, it must also be understood, supported and accepted by those who must employ that technical procedure in cases submitted to the division. Supervisors and Technical Leads will communicate the development plan and progress to the members of their functional area.

Technical procedures must be as well documented as possible. Documentation includes specific literature articles, texts, reviews, and data compilations. A Reference List may be included in either the technical procedures or the training manuals. The procedure should include:

- Definition of terms
- Literature references
- Scope of the analysis conducted

- Standards for notes, interpretation of results and reporting
- Minimum examination requirements
- Equipment/instrument specifications required
- Equipment/instrument operation, maintenance and verification procedures
- QA statement
- Safety statement
- Documented validation studies

Note: Methods currently in use that have been validated by the laboratory, that are of a long standing, historical nature, long predating this ISO-based version of manual, may not have validation documentation on file. The validity of these methods has been repeatedly demonstrated by past and present analytical results and accurate proficiency test results.

All technical procedures shall include provisions for the following:

- Quality control and quality assurance: this includes guidelines for negative controls, knowns, and calibrations, and how they should be reported.
- Test data interpretation
- Be applicable to the submitted item in order to conduct requested analysis
- Defining of ranges of the conclusions that can be drawn from the data
- For test methods involving the comparison of an unknown to a known requiring identifying characteristics for comparison, criteria for the evaluation of the characteristics
- If applicable, evaluation criteria for characteristics suitable for statistical rarity calculations
- Where safety issues exist, safety precautions specific to each technical procedure shall be included in the documentation and incorporated into the technical procedure. Safety should also be a major consideration in the development and acceptance of a technical procedure. Any precautions and limitations of the technical procedure must be documented in the technical procedures manual.

Procedural manuals will include procedures, or make reference to procedures, to ensure safe handling, transport, storage, use and planned maintenance of measuring equipment (i.e., balances, pipettes, calipers, trigger pulls, rulers) to ensure proper functioning and in order to prevent contamination or deterioration.

18.3 USING TECHNICAL PROCEDURES

There are specific technical procedure manuals for each recognized forensic discipline. The official CLD controlled manuals are maintained electronically by the QPM and are readily available to all analysts and staff.

The items submitted to the laboratory and the information needed by the criminal justice system can vary greatly in different cases. If forensic scientists lack knowledge and/or the

available procedures to process certain cases, then they will notify their supervisor who will either refer the analysis to another forensic scientist who has the necessary expertise, or consult available literature, colleagues, and other sources (such as manufacturers, universities, and other agencies) in order to obtain the needed data or technical methodology. If this is not successful because of limited resources, then the report should clearly explain the limitations of the work and that the conclusions were drawn from limited analysis.

Although many acceptable procedures may exist to perform a particular examination, considerable variations in case samples require that forensic scientists have the flexibility to exercise discretion in selecting the method most appropriate to the problem at hand.

19METHOD VALIDATION

19.1 POLICY

The laboratory shall use appropriate methods and procedures for all tests and test data interpretation within its scope and which meet the needs of the customer. Validated methods published in international, regional or national standards or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard method unless there is a documented reason not to do so. The laboratory or discipline will ensure that all non-standard methods, laboratory-developed methods, and modified methods that are significantly modified such that the change(s) affects the outcome of the test are properly validated prior to use. The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

The validation will be as extensive as is necessary to meet the needs of the given application or field of application. All validation studies will be planned and performed with the aid of the Technical Lead or under the direction of the DNA Technical Leader by qualified personnel with adequate resources to perform the validation. The proper validation of a technical procedure requires an understanding of the theoretical basis for the technical procedure. Such knowledge provides a means of assessing the specificity and limitations of the technical procedure and predicting possible sources of error. Results of the validation will be documented and archived. Archival may be as part of the functional area technical manual or in a separate validation binder. The documentation will include the data, the procedure and controls or standards used, a statement as to whether the method is fit for the intended use, and documentation of approving authority.

Prior to implementation of a validated method that is new to the laboratory, the efficacy and reliability of the method shall be demonstrated in-house against all documented performance characteristics of that method. Records of performance verification shall be maintained for reference.

Method validations shall:

- Be a planned activity that is approved and authorized;
- Be reviewed regularly as the validation is carried out, and updated as needed, with any change in requirements requiring modifications to the development plan being approved and authorized;
- encompass the test process to include data interpretation;
- establish the data required to report a test result, opinion, or interpretation;

- identify limitations of the test method, reported test results, opinions, and interpretations;
- specify when a currently validated method, including associated data interpretation, needs additional validation; and
- require a validation plan providing direction for parameter evaluation and parameter acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation.
- Consider costs and risks.

The guidelines below will be used for development of method validation plans.

19.2 PROCEDURE

Prior to beginning any validation study, a validation plan will be prepared by the scientist involved and the discipline Technical Lead/DNA Technical Leader and submitted through the chain of command to the SAS Manager for review and approval. The selection of the appropriate type of validation should be part of the planning process. As the study progresses, the plan will be updated as necessary. Effective communication among all personnel involved including other analysts in the section, the Technical Lead or DNA Technical Leader and the SAS Manager will be accomplished through verbal or written communications.

Laboratory personnel wishing to introduce and validate a new technical procedure, or significantly modify an existing procedure such that the change(s) affects the outcome of the test, shall seek initial approval for development through their supervisor. When drafting a proposal the scientist, Technical Lead/DNA Technical Leader will include the following:

- The basis of the recommendation, including the objective, benefits to the laboratory system and relevance to the customer
- Who is expected to conduct the development and validation
- Where the work will occur
- Compatibility with evidence handling procedures
- Ability to quickly provide accurate data
- Ability of the procedure to produce the most discriminating information
- What equipment will be used
- Compatibility with available equipment, facilities and personnel
- The extent that the procedure destroys, consumes or alters evidence, including compatibility with other procedures which might be used before or after the method for confirmation or other purposes
- The validation plan for the method (see details below)Test samples, standards, certified reference materials and/or reference materials to be used

- How each performance characteristic of the validation that is applicable is going to be evaluated and met
- The estimated costs associated with the development and validation, including supplies, materials and implementation
- Literature research: Review of publications, academic materials, safety procedures, protocols and manufacturer's specifications, etc. involving the technique or procedure being validated
- Source of the technical procedure, if scientific in nature
- Safety Data Sheets (SDS) regarding any chemicals required for the technical procedure
- Timeline for implementation

If the proposal is authorized upon review by the SAS Manager, the validating laboratory will document the validation process. If the validation is successful, the documentation will be sent to the relevant Technical Lead or DNA Technical Leader for review. The Technical Lead or DNA Technical Leader will determine if the new technical procedure has been sufficiently validated and if it should be included in the procedures manual. The procedure will be formatted in preparation for inclusion in the technical manual following the document control process. A copy of the completed validation will be submitted to the SAS Manager.

For equipment method validation, a copy of the validation documentation and data must be kept with the equipment records. The Technical Lead or DNA Technical Leader will prepare an IOC directed to the section supervisor and/or Laboratory Manager, as appropriate, advising them that the equipment method has been validated and is ready for use in casework. By signing and acknowledging the IOC, the Laboratory Manager authorizes the placing of the equipment into service.

19.2.1 Method Validation Plans

In addition to the above considerations, method validation plans will include:

- Objective of the Method
- Equipment Used
- Testing Samples
- Reference Standards and casework samples: The samples used for validation should be representative of the types of casework samples and blanks routinely analyzed using the technique or procedure, and include standards, reference materials and/or certified reference materials. The technical procedure must be tested using known samples. If a new technical procedure is intended to supersede an existing procedure or if it parallels an existing procedure, then the results of both procedures should be compared. The known samples should be designed to resemble actual evidence materials as closely as

possible, taking into account the following (as applicable) matrix, sample age, environmental effects, sample homogeneity and other factors as appropriate to the functional area.

- Applicable performance characteristics
    - ***Accuracy***: The quality or state of being correct; the degree to which the result of a measurement, calculation or specification conforms to the correct value or a standard. Labs should test accuracy by using samples of known values or quality or by comparing results to references of known values or quality.
    - ***Repeatability Precision***: A measure of the variability in results when a measurement is performed by a single analyst using the same equipment over a relatively short timescale (for example, about 6-15 repeats). Repeatability is expected to give the smallest amount of variation in results.
    - ***Reproducibility Precision***: A measure of the variability in results between laboratories using the same method. Reproducibility is expected to give the largest variation in results. The method must be reproducible by another individual using the original test documentation.
    - ***Specificity***: The extent to which the method can be used to determine particular analytes in mixtures or matrices without interferences from other components of similar behavior. Does the method provide results specific to the substrate tested (i.e., What is the occurrence of false positives?).
    - Robustness: A measure of the method's capacity to remain unaffected by small, but deliberate variations in method parameters.
    - ***Sensitivity or Linearity Studies***: This performance characteristic informs the working range of your instrument or test, the limits of detection and range of analysis (lower to upper limits). The goal is to determine a range of which a reliable result can be obtained that is above baseline and interpretable. This is an important characteristic for monitoring quality control of an instrument or test. Is the sensitivity so great that many false positives occur? Is the sensitivity so low that many false negatives occur? Are you working within the linear range of detection? What are the detection limits of the method or instrument?
    - ***Ruggedness***: Assesses the factors external to the method, such as environmental temperature, lighting, humidity and human error. When applicable, evaluate the method using known samples under different environmental conditions.
    - ***Measurement Uncertainty:*** This is a requirement for quantitative validations where the laboratory must have a study of measurement uncertainty performed within any validation that requires measurements that will affect the test result be performed. If the method provides reported quantitative data, the validation study must include an estimate of accuracy and precision at concentrations which are representative of casework samples expected to be encountered when using the method.
    - ***Sources of Error:*** It is important to be clear about any sources of error that occur during the validation. These sources of error will each have to be addressed in the validation report. Known sources of error can come from scientific literature

references used for the method that you are validating such as relevant journal articles

- Timeline for completion
- Documented technical review
- Final report IOC summarizing the validation to include literature references, any sample selection plans and a statement that the method is fit for use.

19.3 PERFORMANCE VERIFICATION

Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use in the laboratory. A performance check tends to mimic an abbreviated validation and is meant to check the accuracy and reliability of equipment and methods. Functional area technical procedure manuals may have additional details on performance verification specific to their testing.

Performance verifications must be completed for the following:

- Methods that have undergone validation and implemented in the CLD laboratory;
- Newly purchased equipment of similar make and model or operating on the same principles or basic technologies as other equipment already implemented and used in the CLD;
- Equipment transferred from one lab to another;
- Regular verification of equipment currently in use to ensure that the instrument/equipment continues to function to manufacturer's specifications and to in-house procedure specifications
- Previously validated methods (e.g. published standard methods) new to a laboratory;
- Other circumstances deemed appropriate by the Technical Lead, DNA Technical Leader or functional area technical procedure manuals.

Performance verification procedures:

- All verification results must be documented, maintained onsite, and will be subject to review during the annual internal audit.
- Verification must demonstrate that a representative set of reference materials has been carried through the process and yielded the expected results.
- The performance verification must have demonstrated in-house the reliability of the method against all documented performance characteristics of the method and shall be maintained for reference.

- The samples used for verification should be representative of the type of standards routinely used for controls and specimens routinely analyzed using the technique or procedure.
- Accuracy and precision studies to verify that the equipment or procedure is within previously established manufacturers or procedure specifications.
- Include estimates of measurement uncertainty for quantitative methods, as applicable.
- For equipment, a copy of the verification results and data must be kept in the equipment log.

19.4 DEVIATION FROM TECHNICAL PROCEDURE

Deviations from the CLD Technical procedures may occasionally be justified.

19.4.1 Deviation

Deviation is a pre-planned change or variation in a technical procedure.

19.4.2 Policy

Any deviations from Division technical procedures must be approved in writing by the SAS Manager and functional area Technical Lead. If the functional area Technical Lead is not available, the appropriate management liaison may approve a deviation in consultation with the SAS Manager. In the DNA functional area, only the DNA Technical Leader's approval (or those designated in the DNA Quality Assurance Manual) is required. The approval must be technically justified and documented in the case file. Deviation from test methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

20 SAMPLING AND SAMPLE SELECTION

20.1 POLICY

The CLD laboratories typically do not engage in statistical sampling of evidence. Instead, analysts select samples for analysis, which may not be a true statistical representation of the whole. Where required, the Technical Lead, or the DNA Technical Leader where appropriate, with input from the supervisors and the Functional Area, will define a sampling plan and procedures for when a discipline must carry out a true sampling of substances, materials or products for subsequent testing. The sampling plan and procedures for sampling will be documented in the specific functional area procedure manual.

20.2 DEFINITIONS

20.2.1 Sampling or Sampling Plan

A defined procedure whereby a part of a substance, material or product is taken to provide for testing as a representative sample of the whole.

20.2.2 Sample Selection

The practice of selecting a sample(s) of the whole based upon training, experience and competence, to draw conclusions and report only on the sample(s) tested.

20.3 PROCEDURE

As applicable, each discipline shall document in its technical procedures manual a sampling plan and procedure for items that require sampling prior to testing. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test results.

Proper selection of analytical materials from evidence will be a result of the individual scientist's training and experience. Sample selection will also be addressed in the training manuals.

Sampling plans should describe the selection, withdrawal, and preparation of a sample or samples from a substance, material or product to yield the required information. The sampling plan and procedure(s) shall:

- Require an evaluation of the selected population for homogeneity;
- Require the population to have a reasonable expectation of homogeneity to use a sampling plan;
- Require that the sampling plan makes use of probability and provides an opinion or interpretation with a minimum confidence level of 95.45% (often referred to as approximately 95%);

- Require each item selected to meet the sampling plan level of confidence to be tested completely; and
- Provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity.

It is appropriate to choose a limited number of samples for analysis from multiple samples if those chosen are representative of the larger sample. Care must be exercised that the analytical results reported are only for the items analyzed and not representative of the whole. No conclusions may be drawn for the whole. For example, if two bags of white powder are analyzed from a submitted sample of 20 bags of white powder of similar appearance, then the report must only reference the results of the analysis of the two bags chosen. Otherwise, a sampling of the whole must be conducted and the sampling method documented, and the results may be applied to the entire quantity of material under investigation.

If the functional area utilizes more than one sampling procedure, the procedure used must be documented in the case file. Deviations from the sampling plan may be requested by the external customer or be deemed appropriate by the analyst. If the supervisor approves a deviation from the sampling plan then this shall be recorded in the case file and communicated to the DNA Technical Leader or applicable technical lead.

As applicable, diagrams or other equivalent means shall be used to illustrate location of sample(s) taken.

As appropriate, documentation of sampling shall include the following:

- The date of sampling
- Unambiguous identification of the substance, material or product sampled
- The location of sampling, including any diagrams, sketches or photographs
- A reference to the sampling plan and procedures used
- Details of any environmental conditions during sampling that may affect the interpretation of the test results
- Any standard or other specification for the sampling method or procedure, and deviations, additions to, or exclusions from the specification concerned
- If necessary for the interpretation of test results and conclusions, the sampling plan used will be included in laboratory reports

21 SUBCONTRACTING OF TESTS

21.1 POLICY

Each contractor or contract laboratory that is employed by the CLD for providing testing services or analysis or technical review will establish competency to perform the contracted work, including provisions for evidence security. A documented technical assessment will be performed, to include a review of their procedures to determine if they meet CLD standards by having the same or equivalent procedures before a contract can be approved. Contractors will review the WSP Regulation Manual and the CLD Quality Operations Manual and relevant Technical Manuals prior to beginning work. Documentation of competency shall be obtained or provided to the CLD prior to submitting samples to a contract laboratory. Contractors and contract laboratory employees designated by the CLD shall be participants in an on-going proficiency testing program provided by an approved outside provider.

All CLD laboratories that receive transfer or referral casework from another CLD laboratory are considered contract labs. All CLD forensic laboratories are considered competent labs and customer requests can be transferred to any WSP lab at the discretion of the individual laboratories.

21.2 DEFINITIONS

21.2.1 Competent Subcontractor

A competent subcontractor is one that is accredited to an appropriate international standard by an accrediting body with a scope of accreditation that covers the services being subcontracted and complies with CLD criteria for the work in question.

21.3 PROCEDURES

The CLD will advise the customer of the subcontracting arrangement in writing and gain approval of the customer, preferably in writing. Convicted offender DNA samples may be contracted out without notification to the collecting agency. DNA sample analysis contracted out by the customer can only be accepted for CODIS consideration if the contract between the customer and the external laboratory has been approved by the DNA Technical Leader prior to the start of analysis. Procedures for outsourcing of DNA analysis are described in the DNA Quality Assurance manual. Communication to the customer regarding the transfer or referral of casework to another CLD laboratory is not required but may be appropriate. If available, a subcontractor shall be accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement with a scope of accreditation that covers the testing services being subcontracted. Any specific requirements for establishing subcontractor competency are found in the procedures or quality manuals of the discipline requiring the subcontractor.

The SAS will maintain a list of contract laboratories being used and their documentation of competency.

21.4 USE OF OUTSIDE EXPERTS

Under certain circumstances the CLD may employ an outside expert. These circumstances include, but are not limited to, consultation in the resolution of technical disagreements, technical reviews of casework, proficiency test preparation, audits, training or other consultations. Use of an outside expert may only be done with the approval of the CLD Commander.

To request the use of an outside expert, a written request must be sent to the CLD Commander to include:

- The scope of work to be performed by the expert
- A CV or resume outlining the expert's qualifications

22 RESEARCH PROJECTS, PUBLICATIONS AND PRESENTATIONS

22.1 POLICY FOR RESEARCH PROJECTS

All research projects employing the use of laboratory resources will be reviewed and approved by the analyst's Laboratory Manager and the Standards and Accountability Section prior to the initiation of the project. This includes research projects for the investigation of new methodology or technology, measurement uncertainty studies, or additional studies on currently used methods.

22.2 PROCEDURE FOR RESEARCH PROJECTS

Prior to beginning any research study, a research plan, including experimental design, will be prepared for review and approval by the discipline Technical Lead or DNA Technical Leader, and then submitted up the chain of command through the Lab Manager, to the management liaison, and to the Standards and Accountability Manager or designee for approval. The selection of the appropriate type of equipment, standards, controls, and reagents should be part of the plan as well as a budget estimate. As the research progresses, the plan will be updated as necessary. Effective communication among all personnel involved, including other analysts in the section, the discipline Technical Lead or DNA Technical Leader, the supervisors, the management liaison and the Quality Assurance Manager will be accomplished through verbal or written communications.

The research plan shall follow the same criteria as those listed for developmental or non-standard method validation.

22.3 POLICY FOR MANUSCRIPTS AND PRESENTATIONS

An individual shall obtain approval from their supervisor prior to working on a manuscript for publication or a presentation of original research. A technically reviewed draft of the manuscripts or presentation of original research must be submitted to the SAS Manager for approval prior to submission of the manuscript to a journal or prior to the presentation. This policy applies specifically to research where the WSP CLD is mentioned in manuscripts for publication or presentations of research, when the author is a representative of the WSP CLD, or when the research or preparation for the presentation occurred on duty time. Final approval shall come from the CLD Commander.

Other types of presentations shall be approved as follows, and do not apply to the Procedures for Manuscripts and Presentations below:

- Criminal justice personnel training (e.g. law enforcement, prosecutors): presenter's supervisor and the applicable Forensic Scientist 4 and management liaison (copy the lab manager)
- Informational presentations to the public (e.g. schools, Rotary): presenter's supervisor (copy the lab manager)

- Internal technical training: Functional Area's Forensic Scientist 4, or for DNA related training, the DNA Technical Leader
- Internal informational (non-training) presentations or manuscripts do not need prior approval (e.g. functional area meeting briefs or those required as part of a training plan).

22.4 PROCEDURE FOR MANUSCRIPTS AND PRESENTATIONS

Technical reviewer(s) do not need to be Division personnel, but may be anyone qualified by training and experience to give a proper review. The technical reviewer's approval shall be documented on the final draft of the manuscript/research presentation.

The final technically reviewed draft of the manuscript/research presentation must be submitted to the SAS Manager for approval at least 14 days prior to the time the manuscript or presentation is sent to a journal or the analyst is making the research presentation. The analyst's supervisor and laboratory manager shall be copied on the communication to the SAS Manager.

At a minimum, the review for approval by the SAS Manager, or designee, will consist of:

- Technical quality and completeness of data: Is there sufficient data of adequate quality to justify inferences?
- Accuracy of the conclusions: Does the data in the manuscript/presentation support the conclusions?
- Proofing of mathematics, spelling, grammar and punctuation;
- Feedback should not consist of the reviewer's perception of the style.

The author must address the reviewer's comments and any differences of opinion will be resolved by consensus.

The approval documentation for a manuscript or research presentation from the technical reviewer, SAS Manager and the CLD Commander is the responsibility of the author.

Approval documentation for slide presentations may be noted on the first slide of the presentation by adding a "New Comment" and entering the electronic signature and date of the approver. Approved slide presentations and handouts may be placed on the FLSB Portal (Crime Lab Division/CLD Documents/Approved Presentation Materials) for use by other CLD staff. Minor modifications (e.g. statistics updates, lab specific information) to approved presentation materials may be approved by the presenter's supervisor.

23 LABORATORY PHYSICAL PLANT AND SECURITY

23.1 PHYSICAL PLANT

In order for the laboratory to efficiently carry out its goals and objectives, adequate and proper space should be allocated for each laboratory activity and function.

The laboratory will have space designated for the safekeeping of official laboratory records and reports as well as space for reference material, books, and other documents necessary for carrying out the functions of the laboratory.

23.2 BUILDING MAINTENANCE AND ENVIRONMENTAL CONDITIONS

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement.

The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they adversely influence the quality of the results. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. The specific environmental requirements are addressed in the functional area technical manuals.

Regularly scheduled housecleaning will take place in each laboratory. Each CLD employee will be responsible for the general cleanliness of their own work area. The laboratory managers will be responsible for the overall cleanliness of their facility.

23.3 SECURITY

23.3.1 Division Policy

The laboratory will be designed and equipped to assure the safety of laboratory personnel, the preservation and integrity of physical evidence, and the protection of the laboratory's assets and records (including computer data). The laboratory will have an alarm system as outlined under "Intrusion Alarms" below. Access to the operational areas of the laboratory will be controlled and limited.

23.3.2 Definitions

23.3.2.1 Areas of Accessibility

Each laboratory facility shall define their areas of accessibility and have guidelines that govern accessibility to those areas. Laboratories differ in design, consequently some areas may, out of necessity, be used for several purposes. The laboratory's security measures must account for multiuse areas and develop procedures to ensure proper security. In general, guidelines should consider the following types of areas:

23.3.2.2 Public Area

An area such as a lobby, common hallway, conference room, or restroom which may be accessed by members of the public during business hours without escort.

23.3.2.3 Evidence Delivery Area

An area designated for members of law enforcement to submit or receive evidence during business hours.

23.3.2.4 Evidence Vault

An area specifically designated for the storage of evidence accessible only by authorized laboratory personnel and escorted departmental auditors and authorized escorted individuals.

23.3.2.5 Evidence Examination Area

An area designated for the examination of evidence which is accessible only to laboratory personnel and authorized escorted visitors.

23.4 SECURING THE LABORATORY

The specific opening and closing procedures for each laboratory will be documented in writing by the Laboratory Manager. Laboratory entry doors and the outside perimeter of the laboratory will be kept secure at all times.

23.5 KEYS, PROXIMITY CARDS, AND COMBINATIONS (ACCESS CONTROL DEVICES)

Laboratory managers or their designees will issue to employees laboratory door and alarm keys or proximity cards, and combinations or codes, as appropriate. Key and proximity card logs will be maintained in accordance with departmental regulations by laboratory managers or their designees, and combinations will be changed as needed to ensure that only authorized individuals have laboratory access. Keys and proximity cards may not be duplicated or loaned, and combinations or codes may not be divulged to unauthorized personnel.

Entrance/exit points and internal areas requiring limited/controlled access will have a lock system. Keys (magnetic cards, etc.) to these locks will be distributed only to employees, or, on a restricted basis, to visitors as noted below (see section on Visitors below). The distribution will be accounted for by the Laboratory Manager or designee in a log. The log may be paper and/or electronic (see WSP Regulation Manual, Section 10.17.010 Access Control Devices (ACD) Accountability).

It is recognized that each laboratory presents a unique security challenge because of its physical location, size, building design, proximity to other state offices and complexity of the security system. At a minimum, the following security criteria will apply:

- The laboratory will be secured during the hours it is vacant by an intrusion alarm

- If a laboratory employee leaves employment in a laboratory equipped with a single laboratory wide alarm code, that alarm code will be changed immediately; if an individual access card had been issued, this card will be immediately deactivated
- If keys or proximity cards are lost, the Laboratory Manager will be immediately notified and appropriate actions to maintain security will be taken
- All evidence will be kept in the evidence vault or a secure storage area during the hours the laboratory is vacant
- Personal firearms are not permitted on WSP sites.

23.6 INTRUSION ALARMS

Each laboratory will have an intrusion alarm system that is monitored at all times. Laboratory managers will create written alarm and emergency response procedures. Such procedures will include:

- The name and location of the alarm monitoring company or agency
- Instructions to the monitor regarding the notification of laboratory, police, and fire personnel
- Procedures to follow in the event of a false alarm or alarm malfunction
- Relevant information regarding the availability of laboratory keys, combinations, or codes that might be used in emergencies (e.g. a key in a sealed envelope). The security of any such key, combination, or code must be verified by laboratory managers at least once per year.

Each Laboratory Manager, or designee, shall conduct a test of the alarm system annually to verify that the alarm system is working. This test can be conducted at any time in the calendar year, but must be at least six months after the prior test. Acceptable methods of performing a test of the alarm system include:

- Intentional test: the system is intentionally 'tripped' by passing a motion detector, etc.
- Accidental test: an employee accidentally 'trips' the system
- Vendor test: a security system vendor is hired to test the system

A log will record all code changes and testing. The log will have the following information:

- Date alarm tested/alarm code changed
- Indication if this is an alarm code change or alarm test
- Zone or area tested (i.e., entry door(s), motion detector, etc.)
- If this is a test, Pass/Fail
- The person who tested/changed alarm

23.7 Fire Alarms

Each laboratory will have smoke and fire detection systems. Evacuation drills will occur at least once per year and will be documented by the laboratory facility safety officer.

23.8 Vault Entry and Secure Areas

Entry into the vault shall be limited to designated laboratory personnel only, except for any unusual situations which must be preauthorized by laboratory managers or their designees. All visitors to the laboratory evidence vault will sign an entry log and will be escorted at all times. Laboratory managers will be responsible for controlling keys and combinations to vault-locking mechanisms.

Evidence lockers for the short-term storage of evidence will be made available to each scientist. Access to keys for short-term storage lockers will be limited to the section scientists and the laboratory manager or their designee. If not in a short-term storage area, any evidence retained outside the laboratory vault must be in a secure area.

23.9 Visitors

Employees of the Forensic Laboratory Services Bureau who visit another FLSB laboratory do not need to sign the visitors log but will have limited access and may need to be escorted in certain areas of the laboratory based upon local laboratory policy. FLSB identification will be displayed at all times.

Non-FLSB employees will be required to sign the visitor log, will have limited access, and may need to be escorted in certain areas of the laboratory, based upon local laboratory policy. Visitor badges will be assigned or law enforcement identification displayed while in the laboratory.

At no time will visitors be given access to evidence vault areas or case files without an escort. Laboratory Managers may limit or allow access to the laboratory in special situations that do not meet the examples listed above.

23.10 DNA Elimination Sample from Visitors

Visitors to analytical areas of a laboratory (instrument technicians, building trades workers, etc.) should be made aware of the following:

- A buccal swab sample is required from visitors to laboratory analytical areas prior to entry. This procedure is to monitor potential DNA contamination which could impact the interpretation of DNA test results. Managers (or their designee) may make an exception to this policy where appropriate (e.g. a brief walk-through or tour groups).

- Unless previously provided, a buccal swab sample for DNA elimination purposes will be collected by a CLD staff member. The DNA sample shall be sent to the CODIS Laboratory for analysis.
- Visitors may request the removal of their DNA profile from the elimination sample database once six months has elapsed since their last laboratory visit. Removal may be requested by sending an email to confel@wsp.wa.gov, listing the visitor's name and the date and location of their last crime lab visit.
- A DNA staff member may also require that a face mask, sleeves, and/or gloves be worn. The personal protective equipment will be provided by the crime laboratory.
- Conversation must be kept to a minimum in order to avoid possible DNA contamination due to talking, sneezing, etc.
- Laboratory space must be kept clean and instrumentation protected from debris. If it is anticipated that the necessary work will produce debris, CLD staff will assist the worker to ensure the lab area is protected.
- Workers shall avoid placing tools, notebooks, etc. on laboratory countertops or instruments unless pre-approved by CLD staff.
- DNA post-amplification room work must be completed at the end of any multi-room project. Tools brought into a DNA post-amplification room shall be cleaned prior to re-use in the crime laboratory.

23.11 OBSERVATION/DOCUMENT REVIEW BY OUTSIDE EXPERTS

Outside experts wishing to observe the examination of evidence or review documents may be allowed on the premises under certain conditions. These conditions are necessary to protect the integrity of the evidence and the work processes carried out by the laboratory.

Visits by outside experts for the purpose of observing evidence examination will be allowed only when there is a limited sample and the analytical procedure will likely consume the entire sample.

23.11.1 First-Time Visit in the WSP Crime Laboratory Division

Experts will be considered for entry onto the premises after they comply with the following, at least 5 working days, dates inclusive, prior to the requested visit:

- a completed "Request for Observation of Examination/Document Review" form is received;
- a completed "Background Qualifications on Outside Expert" form is received;
- a current *Curriculum Vitae* is received.

For any request to observe laboratory examination, a DNA profile from the outside expert is required for purposes of DNA elimination. At the time of the first visit, a buccal swab sample will be collected unless the Crime Laboratory Division already has a DNA profile from the individual. The sample will be typed to obtain an STR profile with, at minimum, the CODIS core loci and added to the elimination database.

23.11.2 Repeated Visits in the WSP Crime Laboratory Division

An expert who has been previously granted permission to observe the examination of evidence or review documents on site in a specific discipline is only required to fill out the "Request for Observation of Examination/Document Review" form. The completed form must be received at least 5 working days prior to a requested visit, dates inclusive. The visit must be in the same discipline as previously granted permission, but can be at different laboratories within the crime laboratory division.

Outside experts may request the removal of their DNA profile from the elimination sample database once six months has elapsed since their last laboratory visit. Removal may be requested by sending an email to confel@wsp.wa.gov, listing the outside expert's name and the date and location of their last crime lab visit.

The Laboratory Manager will assess each request and can deny the request based on information provided at the time the request is made or based on information provided from previous denials.

While making an authorized visit, outside experts are not allowed to use state-owned equipment to conduct their own independent testing, but may use state-owned equipment insofar as it is necessary to observe the testing being conducted or to view the data collected.

Outside experts may be permitted to photograph, or otherwise record only images of evidence items related to the case, but are not permitted to record images of laboratory personnel or evidence related to a different case. The time allowed for recording evidence images is limited to no more than 15 minutes per item. No videotaping will be permitted.

23.11.3 Interviewing Employees

Interviews of employees by media, defense attorneys, or others as deemed appropriate, are allowed only insofar as the employee agrees to be interviewed and the interview process does not have a deleterious effect on the laboratory's efficiency and resources. Interviews will conform to the following standards:

- Interviews of employees will be prescheduled and conducted with minimum impact to employees' work assignments;
- All interviews will be conducted in a courteous and professional manner;
- A maximum of two hours will be allowed for any interview. If additional time is needed, the employee may opt to extend the interview or a second interview may be scheduled;
- Employees have the authority to stop or pause an interview for a rest break, or if they become uncomfortable for any other reason;
- Employees may consult with their supervisor or laboratory manager at any time, and may opt to terminate an interview if appropriate. They may also opt to have the supervisor or manager present during the interview.

23.12 LAPTOP SECURITY

Many personnel are issued laptops for the purpose of offering mobility to their work. Because these agency laptops contain sensitive information, it is incumbent upon the custodian of the laptop to exercise due diligence in protecting the device from theft, loss, or damage. As with all agency computers, when stepping away from the laptop the custodian must, at a minimum, lock the keyboard or log off. If the laptop must be left in a vehicle, it should be locked in a trunk. If this is not possible, as in a station wagon, the laptop will be covered or concealed. Care should be used during travel (airline, train, etc.) that sensitive information cannot be inadvertently viewed by the general public. The same is true for employees who use their laptop at home and reside with people who are not crime lab employees. When staying in a hotel room or in similar situations, if the laptop is left in the room, ensure the laptop is concealed or otherwise not out in the open.

Should the laptop become lost or stolen, the employee will follow the procedure outlined in the WSP Regulation Manual (see section 18.00.060 – Loss or Damage of Department Property and Equipment).

24 HEALTH AND SAFETY

It is important that the CLD establishes and maintains a health and safety program that is designed to safeguard employees from service-related injury and health problems. The CLD health and safety program is documented in the CLD Safety Manual.

Ultimate responsibility for the health and safety program lies with the Division Commander, who along with the Laboratory Managers must provide continuing support and monitoring. The Division Commander and the Laboratory Managers draw upon the CLD Safety Officer and CLD Safety Committee personnel for technical support and assistance. The CLD Safety Committee will be developed along the procedures outlined in the WSP Safety and Wellness Manual and the Collective Bargaining Agreement.

Laboratory Managers will ensure performance of mandatory safety drills specified in the Safety Manual. All personnel are required to be aware of the plan and to follow procedures as situations arise.

It is the responsibility of the Laboratory Manager to ensure compliance with the Safety Manual. The Safety Committee is responsible for conducting and documenting annual safety audits. Each Safety Officer serves as a member of the CLD Safety Committee, chaired by the CLD Safety Officer, which will meet at least annually for the purposes of reviewing and updating the Safety Manual, discussing division-wide safety issues, and making recommendations to management for improving the division's chemical hygiene and safety goals. Minutes of the Safety Committee meetings will be posted on the FLSB Portal for review.

Any laboratory staff member has the responsibility to notify the Safety Officer, Section Supervisor and/or the Lab Manager of any practice felt to be unsafe.

The Laboratory Manager is responsible for advising the Quality Process Manager and the CL Division Commander of unsafe practices and the corrective measures implemented. Each laboratory shall have emergency evacuation plans developed and posted in general areas in the laboratory. The Safety Officer should schedule, implement, and document annual evacuation drills.

CLD employees will review the Safety Manual on an annual basis. This review will be documented on the CLD Safety Orientation Checklist (CLD-SAF-15001), to be retained in each laboratory.

Health and safety issues will be included in each employee's Position Description Form (PDF), and they will be evaluated on their performance and their conformance to safety policy.

24.1 SAFETY AUDIT

The Safety Committee will audit each laboratory on a yearly basis, confirming adherence to the Safety Manual. The safety audit report will be retained with other audit reports.

24.2 SAFETY TRAINING

Each laboratory will be responsible for maintaining documentation of safety training for its employees. (See CLD Safety Manual).

25 APPENDIX 1: ROOT CAUSE ANALYSIS GUIDELINES AND PROCEDURES

Root cause analysis (RCA) is used to define, evaluate and systematically analyze a problem to determine the underlying factor(s) or reason(s) for the problem in order to focus on prevention and continued improvement of the system or process. It is important to realize that a root cause analysis is an event review, not a performance evaluation, and the purpose is learning, not punishment. Accordingly, personnel and disciplinary issues should be handled through a separate process from RCA.

25.1 JUST CULTURE

The CLD embraces a method of root cause analysis that creates a "just culture". A "Just culture":

- Is a culture of learning
- Recognizes that competent professionals make mistakes, but holds individuals accountable for reckless behavior. Holding people accountable by punishing them for human error is not going to advance the culture of learning.
- Balances blame-free event reviews with the need for professionals to be personally accountable for adherence to reasonable standards of professional conduct
- Balances an open and honest reporting environment with a quality learning environment and culture
- Fosters learning that will embed knowledge (lessons-learned) that may help prevent similar problems from occurring in the future
- Fosters continuous improvement

Root cause analysis may be the most difficult part of establishing proper corrective actions following the reporting of a nonconformity. By becoming skillful at investigating and solving problems of nonconformity in their work, a laboratory will ultimately need to conduct fewer investigations. But if done inappropriately, a root cause analysis investigation may lead to the inadvertent blame of individuals instead of identifying where a work process has broken down. Such blame will be detrimental to encouraging participation in the root cause analysis process.

The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made to mitigate the identified causes of the problem and reduce the likelihood of recurrence.

RCAs are conducted by the individual(s) assigned by the SAS as the investigator. RCAs may be performed by a team, Technical Lead, Supervisor, Lab Manager and/or other subject matter expert. The number of participants conducting the RCA may vary depending on the nature of the nonconformity.

25.2 PROCEDURE

25.2.1 Step 1: Identifying the Problem

The event, or nonconformance, should be clearly defined and analyzed for its causal factors. This entails a detailed review of the event by the investigator. The analysis and review is conducted to identify problems – what went wrong, what is the problem? The investigation normally begins with the objective stating of the problem. The problem statement is a concise, complete, and accurate single sentence describing what the problem or nonconformity is. Examples include:

- the proficiency test was not passed;
- the case file is missing documentation;
- the wrong individual was identified;
- the sample was contaminated; and
- the results from a different case were reported.

Be sure to start with a problem and not the solution. It is tempting to assume we know what will fix the problem before we've thoroughly examined it. Assumptions are often wrong and may hinder complete analysis of the underlying causes.

The investigator should not define the problem as a need for something. The problem statement should objectively state what went wrong, not why, or how. A good problem statement will facilitate a more thorough examination of the problem.

One tactic in formulating a problem statement is to work backwards from the point of not meeting a known policy, procedure, r goal or objective of the organization. When a determination of what objectives were impacted is completed, the problems affecting the objectives may be more discernable and the problem statement more readily drafted.

Collect and organize the facts surrounding the event to understand what happened. It is often helpful to create a detailed timeline of events pertaining to and leading up to the nonconformance. The investigator should consider reviewing equipment logbooks, instrument data, case files, procedures and policies, previous occurrences and any trends.

The investigator should interview personnel involved. It is important to get the perspective of people personally involved in the event since people naturally see and interpret things differently. Bring all parties involved in the problem in early so it fosters the non-punitive and problem solving nature of RCA investigations. Keep it transparent, focused, simple, and engaging. It may be helpful to provide a brief review of the process before starting the interview or discussion.

25.2.2 Step 2: Identify Root Causes

In this step, the investigator determines why something went wrong. The contributing factors, situations, circumstances or conditions that led to or increased the likelihood of

the event are identified and analyzed. In this step, the investigator must be both focused and open-minded.

A thorough analysis of contributing factors leads to identification and understanding of the underlying process and system issues (root causes) of the event. Contributing factors are not necessarily the root causes. The investigator must examine the contributing factors to find the root causes. A timeline should be used whenever possible as the basis for identifying all contributing factors. When identifying contributing factors, be careful to avoid "hindsight bias." Knowing the eventual outcome of a timeline can influence how the investigator views activities leading up to the event. The investigator should consider only those factors that were actually present and known to those involved at the time, not what was only realized after-the-fact.

The investigator must determine if they've truly identified a root cause, versus a contributing factor which would require more digging. Ask the following questions for each potential root cause identified:

- Would the event have occurred if this cause had not been present?
- Will the problem recur if this cause is corrected or eliminated?

If the answer is NO, then the investigator has identified a root cause. If the answer to any question is YES, then the investigator may not have identified a true root cause and needs to ask more "why" questions. Continue asking these questions until you get to root causes. There may be multiple root causes.

The investigator should not make judgments about whether an individual did the right thing. This judgment is to be made by the supervisor and manager responsible for evaluating the employee's performance.

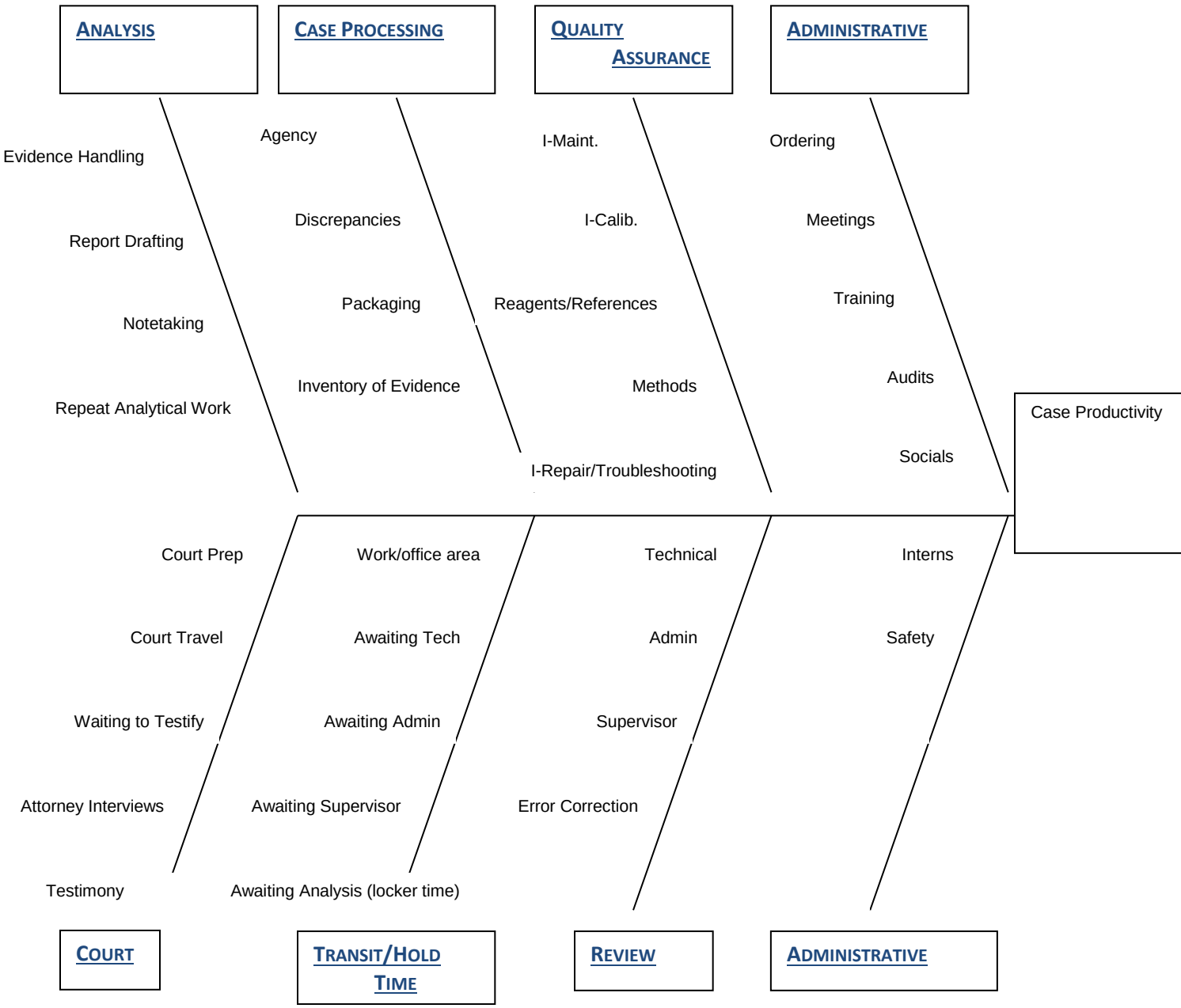
At least one of the RCA tools mentioned below must be used.

25.2.2.1 RCA Tools

There are various approaches to RCA and some may be more effective than others depending on the nonconformity. Brainstorming and creating a cause and effect diagram are two such tools to determine problem statements and root causes. Using a cause/effect diagram while brainstorming possible causes to a problem helps one to focus on the various possibilities. This "Cause Mapping" can be used as a visual technique for capturing the cause and effect relationships in order to lead one back to the root cause(s). First identify the effect (problem statement), then list all possible causes. Some useful categories of causes include:

- People (health, training/skills, time management, knowledge of policies and procedures, etc.)
- Materials and supplies (lack of correct/complete forms, lack of appropriate containers, improper packaging, etc.)

- Procedures/methods (incorrect order of steps, incorrect application of procedure, etc.)
- Environment (HVAC failure, freezer water pipe burst, etc.)
- Equipment/instruments (ran out of gas, CE shut down, etc.)
- Below is an example of a cause and effect “fishbone” diagram (I = Instrument):


ANALYSIS
CASE PROCESSING
QUALITY ASSURANCE
ADMINISTRATIVE
Evidence Handling
Report Drafting
Notetaking
Repeat Analytical Work
Agency
Discrepancies
Packaging
Inventory of Evidence
I-Maint.
I-Calib.
Reagents/References
Methods
I-Repair/Troubleshooting
Ordering
Meetings
Training
Audits
Socials
Case Productivity
Court Prep
Court Travel
Waiting to Testify
Attorney Interviews
Testimony
Work/office area
Awaiting Tech
Awaiting Admin
Awaiting Supervisor
Awaiting Analysis (locker time)
Technical
Admin
Supervisor
Error Correction
Interns
Safety
COURT
TRANSIT/HOLD TIME
REVIEW
ADMINISTRATIVE

Another common RCA tool is "5 Whys". Starting with the problem statement, the investigator asks "Why (did this process fail)?" repeatedly until the root cause is identified. This questioning process is continued until all the root causes are found. The "5 Why's" process can also be used as part of a cause and effect diagram as discussed above. It is common to find the same root cause for two or more contributing factors. For example:

Problem statement: Analysis of an evidence item was not completed by the deadline.

1. Why? The instrument failed to complete the run.
2. Why? The instrument ran out of carrier gas.
3. Why? The tank of carrier gas emptied mid-run.
4. Why? More gas was not ordered.
5. Why? An employee forgot to order more gas.

Three basic types of root causes are:

1. Physical causes – Tangible, material items failed in some way (e.g., the GC stopped working).
2. Human causes – People did something wrong or did not do something that was needed. Human causes typically lead to physical causes (e.g. the GC ran out of carrier gas).
3. Organizational causes – A system, process, or policy that people use to make decisions or do work, is faulty (e.g. the employee did not receive instruction on how to order more carrier gas).

Each root cause must be addressed in the corrective action plan.

25.2.3 Step 3: Develop a Corrective Action Plan (CAP)

The RCA is shared with the individual assigned the CAP by SAS, which may or may not be the individual assigned the RCA. The CAP will include the result of the RCA, corrective/preventive actions, and a timeline to implement the plan and report results of the implementation. The investigator should make specific, prioritized recommendations for preventive actions that are intended to prevent occurrences of similar events. These recommendations will be made in writing and submitted to the individual assigned the corrective action plan if different from the investigator.

To create the CAP, prioritize the factors that contributed to the nonconformance, evaluating both their severity and the probability of recurrence. The CAP will describe corrective actions (including preventive) that respond to the prioritization and likelihood of repetition of the root causes. Choose actions that address each root cause. These actions will generally require creating a new procedure or making a change to a current process.

When developing corrective actions, consider questions such as:

- What safeguards are needed to prevent this root cause from happening again?
- What contributing factors might trigger this root cause to reoccur? How can we prevent this from happening?

- How could we change the way we do things to make sure that this root cause never happens?
- If an event like this happened again, how could we stop the accident trajectory (quickly catch and correct the problem) before its severity escalates?

Aim for corrective actions with a stronger or intermediate rating, based on the categories of actions below. Corrective actions that change the system and do not allow the errors to occur are the strongest.

Stronger Actions

- Change physical surroundings
- Testing of equipment before purchasing
- Engineering controls into system (forcing functions which force the user to complete an action)
- Simplify process and remove unnecessary steps
- Standardize equipment or process

Intermediate Actions

- Make software enhancements/modifications
- Eliminate or reduce distractions
- Create checklist or other cognitive aid
- Eliminate look alike and sound alike terms
- "Read back" to assure clear communication
- Enhance documentation/communication

Weaker Actions

- Double checks
- Warnings and labels
- New procedure/policy
- Training
- Additional study/analysis

If a particular action cannot be accomplished due to current constraints (e.g. lack of resources), the RCI or individual assigned the CAP should look for other ways of changing the process to prevent a similar event from occurring in the future. Doing nothing should not be an option.

When developing corrective action plans, clearly state what is to be done, by whom, and when. Satisfactory implementation of the corrective action plan will be monitored so it is important to have clearly defined plans with timelines.

25.2.4 Step 4: Evaluation

Corrective actions will be monitored through annual internal audits or as detailed in the CAP. Was the CAP properly implemented and effective? This evaluation is summarized in the Corrective Action Report.